No. 12665

United States
Court of Appeals
for the Ninth Circuit.

UNITED STATES OF AMERICA,
Appellant,

vs.

EL-O-PATHIC PHARMACY, MARTIN A. CLEMENS, HUDSON PRODUCTS COMPANY, MAYWOOD PHARMACAL COMPANY and ALLEN H. PARKINSON,
Appellees.

Transcript of Record
In Two Volumes
Volume I
(Pages 1 to 462)

Appeal from the United States District Court, Southern District of California, Central Division.

Phillips & Van Orden Co., 870 Brannan Street, San Francisco, Calif.

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[Clerk's Note: When deemed likely to be of an important nature, errors or doubtful matters appearing in the original certified record are printed literally in italic; and, likewise, cancelled matter appearing in the original certified record is printed and cancelled herein accordingly. When possible, an omission from the text is indicated by printing in italic the two words between which the omission seems to occur.]

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NAMES AND ADDRESSES OF ATTORNEYS

For Appellant:

ERNEST A. TOLIN,
United States Attorney,

CLYDE C. DOWNING,

GEORGE E. DANIELSON,
Assistants U. S. Attorney,

600 U. S. Post Office & Court House Bldg.,
Los Angeles 12, Calif.

For Appellees:

EUGENE M. ELSON,

541 S. Spring St.,
Los Angeles 13, Calif.

In the United States District Court for the Southern District of California, Central Division

Civil Action No. 10266-PH

UNITED STATES OF AMERICA,
Plaintiff,

vs.

EL-O-PATHIC PHARMACY, a Corporation, and MARTIN A. CLEMENS, an Individual,
Defendants.

COMPLAINT FOR INJUNCTION

[21 U.S.C. 332(a), 331(a) and (k), 352(a), 352(f)(1) and (2), 352(j)]

United States of America, plaintiff herein, by and through James M. Carter, United States Attorney for the Southern District of California, Central Division, respectfully represents to this Honorable Court as follows:

1. This proceeding is brought under section 302(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 332(a)], hereinafter referred to as the "Act," specifically vesting jurisdiction in the several United States District Courts to restrain violations of section 301 of said Act [21 U.S.C. 331] as hereinafter appears more fully.

2. The defendant, El-O-Pathic Pharmacy, Inc., is a corporation having its principal place of business at 1109½ No. Western Avenue, Hollywood, California. The defendant, Martin A. Clemens,

is the manager and director of said El-O-Pathic Pharmacy, Inc., and is primarily responsible [2*] for the policies and activities of the firm.

3. Said El-O-Pathic Pharmacy, Inc., and Martin A. Clemens are distributors of certain male and female hormone drugs; the male hormone drugs consist of methyl testosterone tablets (10 milligrams and 25 milligrams) and methyl testosterone in linguet form (5 milligrams and 10 milligrams); the female hormone drugs consist of various preparations containing alpha-estradiol (ranging from .01 milligrams to .5 milligrams).

4. Said male and female hormone drugs are manufactured by Ciba Pharmaceutical Products, Inc., Summit, New Jersey, by Roche-Organon, Inc., Nutley, New Jersey, and by Schering Corporation, Bloomfield, New Jersey, and are shipped in interstate commerce by said manufacturers to said defendants. During the interstate and intrastate journeys of said drugs from the manufacturers to the defendants, the labeling of each such drug bears the legend: "Caution: To be dispensed only by or on the prescription of a physician."

5. In the sale and distribution of said drugs, defendants do not require a physicians prescription. Instead, defendants repackage and relabel said drugs and offer them for sale without a physician's prescription. For example, the 10 milli-

*** Page numbering appearing at foot of page of original Certified Transcript of Record.**

gram methyl testosterone linguets are relabeled as follows:

El-O-Pathic Hormones
50 Tablets
Each Tablet Contains
10 Mg. Methyl Testosterone

Suggested Dosage: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

Directions: For use by adult males deficient in male hormone [3] when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by El-O-Pathic Pharmacy
1109½ No. Western Ave. Hollywood 27, Calif.
Hollywood 9-1722

(Read Side Panels)

[Side Panels]

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution

should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

6. In window and store displays and in newspaper advertising, defendants represent and suggest that said drugs are efficacious in alleviating a variety of disease conditions, especially those allegedly relating to sexual impotence in men and to change of life in women.

7. Said defendants are also circularizing former customers offering the methyl testosterone linguets in quantities up to 1000, to be purchased before said defendants' "Mail Order Department" is [4] discontinued on September 15, 1949.

8. Defendants violate section 301(k) of the Act [21 U.S.C. 331(k)] by causing the 10-milligram methyl testosterone linguets to become misbranded while held for sale after shipment in interstate commerce, in the following respects:

(a) Within the meaning of section 502(f)(1) of the Act [21 U.S.C. 352 (f)(1)] in that the printed matter which defendants cause to

become the labeling of said linguets fails to bear adequate directions for use since it fails to state all of the diseases or conditions of the body for which the drug is intended.

(b) Within the meaning of section 502(f)(2) of the Act [21 U.S.C. 352(f)(2)] in that the printed matter which defendants cause to become the labeling of said linguets fails to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling is couched is inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of a cancer of the prostate gland or may cause sterility.

(c) Within the meaning of section 502(j) of the Act [21 U.S.C. 352(j)] in that said linguets are dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in the printed matter which defendants cause to become the labeling of said drug, since such use of the drug may result in sterility, and may accelerate the malignant growth of a cancer of the prostate gland. [5]

9. Defendants further violate section 301(a) of the Act [21 U.S.C. 331(a)] by causing the introduc-

tion into interstate commerce of said 10-milligram methyl testosterone linguets misbranded in the same respects as described in paragraph 8(a), (b) and (c) above.

10. With respect to the 5-milligram methyl testosterone linguets, labeled exactly as described in paragraph 5 except that 5 mg. is substituted for 10 mg., defendants violate section 301(k) of the Act [21 U.S.C. 331(k)] by causing said linguets to become misbranded while held for sale after shipment in interstate commerce, in the following respects:

(a) Within the meaning of section 502(a) of the Act [21 U.S.C. 352(a)] in that the printed matter which defendants cause to become the labeling of said linguets is false and misleading since it represents and suggests that one tablet daily is efficacious for use in the treatment of male hormone deficiency, whereas one tablet daily would be entirely ineffective for that purpose.

(b) Within the meaning of section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] in that the printed matter which defendants cause to become the labeling of said linguets fails to bear adequate directions for use since it fails to state all of the diseases or conditions of the body for which the drug is intended.

(c) Within the meaning of section 502(f)(2) of the Act [21 U.S.C. 352(f)(2)] in that the printed matter which defendants cause to become the labeling of said linguets fails to bear adequate warnings against use in those

pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling is couched is inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of a cancer of the prostate [6] gland or may cause sterility.

11. Defendants further violate section 301(a) of the Act [21 U.S.C. 331(a)] by causing the introduction into interstate commerce of said 5-milligram methyl testosterone linguets misbranded in the same respects as described in paragraph 10(a), (b), and (c) above.

12. With respect to the methyl testosterone tablets, it is likely that the defendants will cause the same violations of section 301(a) and (k) of the Act [21 U.S.C. 331(a) and (k)] as they are causing with respect to the methyl testosterone linguets (as described in paragraphs 8 and 9 above), since the tablets have the same dangerous potentialities as the linguets; and since the defendants have in the past sold these products freely, without a physician's prescription, and without adequate warnings.

13. With respect to the alpha-estradiol preparations, it is likely that the defendants will cause the same violation of section 301(a) and (k) of the Act [21 U.S.C. 331(a) and (k)] as they are causing with respect to the methyl testosterone linguets (as

described in paragraphs 8 and 9 above), since the unrestricted use of alpha-estradiol preparations by women may accelerate the malignant growth of cancer of the breast, crevix, and uterus, and may cause injury to the female generative system; and since the defendants have in the past sold these products freely, without a physician's prescription, and without adequate warnings.

14. In the case of United States v. El-O-Pathic Pharmacy and Martin A. Clemens, No. 20596-Criminal, this Court on July 13, 1949, convicted said defendants for the distribution of misbranded male and female hormones in violation of the Act. The hormones there involved included methyl testosterone linguets, methyl testosterone tablets, and an alpha-estradiol preparation. In announcing judgment, the Court stated it was convinced beyond a reasonable doubt that these hormone preparations constitute not merely a potential danger but also an actual danger to health when used indiscriminately by the lay person. The Court also stated that the therapeutic claims which defendants made for their products far exceeded the benefits that could be derived from them.

15. Within a month after the aforesaid conviction, defendants have [7] embarked upon a widespread promotion of some of the same products in essentially the same misbranded condition as were the products involved in the criminal prosecution. Defendants' revision of the labeling is merely a subterfuge by which they hope to deceive the Court and defraud the public.

16. The plaintiff is informed and believes that unless restrained by the Court, the defendants will continue to introduce and deliver for introduction into interstate commerce the said articles of drug misbranded in the manner aforesaid, and will continue to do those acts, while holding said drugs for sale after shipment in interstate commerce, which result in misbranding in the manner aforesaid.

Wherefore, plaintiff prays:

That the defendants, El-O-Pathic Pharmacy, Inc., a corporation and Martin A. Clemens, an individual, and each and all of their officers, agents, servants, employees, and attorneys, and all persons in active concert or participation with any of them, be perpetually enjoined from directly or indirectly causing to be introduced or delivered for introduction into interstate commerce, in violation of section 301(a) of the Act [21 U.S.C. 331(a)] the articles of drug, hereinbefore described, or any similar articles, misbranded within the meaning of sections 502(a), 502 (f)(1) or (2), or 502(j) of the Act [21 U.S.C. 352(a), 352 (f)(1) or (2), or 352(j)];

That the said defendants and all other persons hereinabove enumerated be further perpetually enjoined from directly or indirectly causing any act to be done with respect to the articles of drug, hereinbefore described, or any similar articles, while said drugs are held for sale after shipment in interstate commerce, in violation of section

301(k) of the Act [21 U.S.C. 331(k)], which causes any of said drugs to become misbranded within the meaning of sections 502(a), 502(f)(1) or (2), or 502(j) of the Act [21 U.S.C. 352(a), 352(f)(1) or (2), or 352(j)];

That a Temporary Restraining Order be granted without notice to the defendants restraining the defendants as prayed herein, since as shown by the attached affidavits immediate and irreparable injury, loss, and damage will result to the plaintiff before notice can be served and a hearing had thereon;

That at the earliest possible time during the effectiveness [8] of the Temporary Restraining Order, an order be made and entered directing the defendants to show cause, at a time and place to be designated in such order, why they should not be restrained as herein prayed during the pendency of this action; that upon the hearing of said order to show cause, a Preliminary Injunction be granted restraining the defendants as herein prayed during the pendency of this action;

That the plaintiff be given judgment for its costs herein and for such other and further relief as to the Court may seem just and proper.

/s/ JAMES M. CARTER,
United States Attorney.

[Endorsed]: Filed September 2, 1949. [9]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF CLINTON HOBART THIENES, M.D.

United States of America,
Southern District of California—ss.

State of California,
County of Los Angeles.

Before me, Ola H. Bain, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Clinton Hobart Thienes, M.D., in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am a licensed physician in the State of California with the degree of Doctor of Medicine from the University of Oregon Medical School and the degree of Ph.D. in pharmacology from the Stanford University Medical School.

(2) I am Chairman of the Department of Pharmacology at the University of Southern California Medical School.

(3) Pharmacology is the science of the study and action of drug and other products in the treatment of disease.

(4) I have been engaged in the private practice of internal medicine with offices at 2007 Wilshire Blvd., Los Angeles, California.

(5) The drugs, methyl testosterone linguets, methyl testosterone [10] tablets, and alpha-estradiol preparations, are highly potent and, within restricted limits, they have dramatic value in the treatment of some disease conditions. However, they do not have general widespread therapeutic value.

(6) The danger in the use of methyl testosterone linguets and methyl testosterone tablets in men lies in the fact that they may cause sterility and may accelerate the growth of cancer of the prostate gland.

(7) The danger in the use of alpha-estradiol preparations in women lies in the fact that they may accelerate the growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system.

(8) None of these drugs should be used except upon two conditions: (a) careful diagnosis by a competent physician to determine that there is actual need for the drugs, and (b) examination by a competent physician before administration and at regular intervals during administration, to detect the possibility of cancerous growth. In addition, men given methyl testosterone should be warned as to the danger that sterility may result from continued use, and women given alpha-estradiol should

be examined at regular intervals to detect the possibility of injury to the female generative system.

(9) These drugs should not be distributed to lay persons without a physician's prescription because lay persons are not competent to diagnose the hormone deficiency condition which indicates the need for such a drug, nor is the lay person competent to diagnose the presence of cancerous growth which would contraindicate the use of such a drug.

(10) Distribution of these drugs to lay persons without a physician's prescription is a menace and a hazard to the public, and through their insidious effects they may cause widespread suffering and death.

/s/ CLINTON HOBART THIENES,
M.D.

Subscribed and sworn to before me at Los Angeles, California, this 2nd day of September, 1949.

/s/ OLA H. BAIN,
Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed September 2, 1949. [11]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF ELMER BELT, M.D.

United States of America,
Southern District of California—ss.

State of California,
County of Los Angeles.

Before me, Ola H. Bain, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Elmer Belt, M.D., in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am a licensed physician in the State of California with the degree of Doctor of Medicine from the University of California, in 1920.

(2) I did post-graduate work in Urology at the University of California and at Harvard University.

(3) I have specialized in the practice of urology since 1922. I have observed over 1000 cases of cancer of the prostate. I have published a number of scientific papers and books on diseases of the genito-urinary tract.

(4) Urology is that branch of medicine that deals with the male urinary and generative system, and the female urinary system.

(5) I am a member of the California State Board of Health. [12]

(6) The drugs, methyl testosterone linguets, methyl testosterone tablets, and alpha-estradiol preparations, are highly potent and, within restricted limits, they have dramatic value in the treatment of some disease conditions. However, they do not have general widespread therapeutic value.

(7) The danger in the use of methyl testosterone linguets and methyl testosterone tablets in men lies in the fact that they may cause sterility and may accelerate the growth of cancer in the prostate gland. It is estimated from post-mortem investigations that up to one-third of the men over 50 have a dormant cancerous growth in the prostate that may always remain dormant. However, the administration of methyl testosterone linguets or tablets greatly enhances the likelihood that such dormant cancerous growth will flare up into activity and endanger the health and life of the individual.

(8) None of these drugs should be used except upon two conditions: (a) careful diagnosis by a competent physician to determine that there is actual need for the drugs, and (b) examination by a competent physician before administration and at regular intervals during administration, to detect the possibility of cancerous growth. In addition, men given methyl testosterone should be warned as to the danger that sterility may result from continued use.

(9) These drugs should not be distributed to lay persons without a physician's prescription because lay persons are not competent to diagnose the hormone deficiency condition which indicates the need for such a drug, nor is the lay person competent to diagnose the presence of cancerous growth which would contraindicate the use of such a drug.

(10) Distribution of these drugs to lay persons without a physician's prescription is a menace and a hazard to the public, and through their insidious effects they may cause widespread suffering and death.

(11) The administration of 5 milligrams of methyl testosterone linguets daily is wholly worthless in the treatment of male hormone deficiency because this amount of testosterone is therapeutically insignificant.

(12) The administration of 10 milligrams of methyl testosterone linguets daily subjects the lay purchaser and user to all of the hazards above described. [13]

/s/ ELMER BELT, M.D.

Subscribed and sworn to before me at Los Angeles, California, this 2nd day of September, 1949.

/s/ OLA H. BAIN,
Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed September 2, 1949. [14]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF IAN MacDONALD, M.D.

United States of America,
Southern District of California—ss.

State of California,
County of Los Angeles.

Before me, Ola H. Bain, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Ian MacDonald, M.D., in the County and State aforesaid, who being first duly sworn, deposes and says:

(1) I am a licensed physician in the State of California with the degree of Doctor of Medicine from McGill University in 1928.

(2) I have had 6½ years of post-graduate training in surgery and surgical pathology.

(3) I am a member of the Cancer Committee of the American College of Surgeons, and am one of 45 collaborators working under the Therapeutic Trials Committee investigating the treatment of cancer.

(4) I am coordinator of cancer teaching at the University of Southern California.

(5) I specialize in the treatment of cancer and allied diseases. I have diagnosed and treated approximately 1000 cases of cancer of the breast [15] in women and have reviewed the histories of about 2700 other cases of cancer of the breast.

(6) The drugs, methyl testosterone linguets, methyl testosterone tablets, and alpha-estradiol preparations, are highly potent and, within restricted limits, they have dramatic value in the treatment of some disease conditions. However, they do not have general widespread therapeutic value.

(7) The danger in the use of alpha-estradiol preparations in women lies in the fact that they may accelerate the growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system.

(8) None of these drugs should be used except upon two conditions: (a) careful diagnosis by a competent physician to determine that there is actual need for the drugs, and (b) examination by a competent physician before administration and at regular intervals during administration, to detect the possibility of cancerous growth.

(9) These drugs should not be distributed to lay persons without a physician's prescription because lay persons are not competent to diagnose the hormone deficiency condition which indicates the need for such a drug, nor is the lay person competent to diagnose the presence of cancerous

growth which would contraindicate the use of such a drug.

(10) Distribution of these drugs to lay persons without a physician's prescription is a menace and a hazard to the public, and through their insidious effects they may cause widespread suffering and death.

/s/ IAN MacDONALD, M.D.

Subscribed and sworn to before me at Los Angeles, California, this 2nd day of September, 1949.

/s/ OLA H. BAIN,
Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed September 2, 1949. [16]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF ROBERT S. ROE

United States of America,
Southern District of California—ss.

Robert S. Roe, being first duly sworn, deposes and says that he is Chief, Los Angeles District, Food and Drug Administration, Federal Security Agency, and that the following facts and documents are derived from his personal knowledge and from the official records of the Food and Drug Administration in his possession:

(1) On July 13, 1949, the El-O-Pathic Pharmacy, 1109½ North Western Avenue, Hollywood,

California, and its manager and director, Martin A. Clemens, were convicted in this Court of violating the Federal Food, Drug, and Cosmetic Act. (No. 20596-Criminal). The substance of the charges upon which defendants were convicted was the indiscriminate sale of dangerous drugs for lay use together with the making of extravagant therapeutic claims for those drugs. The drugs involved in that case were male and female sex hormone preparations including methyl testosterone linguets, methyl testosterone tablets, and alpha-estradiol preparations.

(2) El-O-Pathic Pharmacy and Martin A. Clemens continue to obtain these drugs from manufacturers in New Jersey. Each such drug when shipped interstate from the manufacturer to El-O-Pathic Pharmacy and Martin A. Clemens is labeled with a prescription legend, namely, "Caution: To be dispensed only by or on the prescription of a physician." The practice of these defendants [20] has been to promote large scale distribution of these drugs by creating the impression through labeling and newspaper advertising that such drugs have miraculous powers of sexual rejuvenation for men over 40, and that they will alleviate disease conditions in women caused by change of life. Said defendants do not require a physician's prescription.

(3) The current methods of distribution adopted by the defendants with respect to methyl testosterone linguets subsequent to their conviction last

month are described in paragraphs 5, 6, and 7 of the Complaint in the instant case.

(4) Attached hereto as Exhibit A is a copy of a letter, dated July, 1947, sent to the defendants and all other distributors of its products by Roche-Organon, Inc., a manufacturer of the drugs here involved. The original of this Exhibit was introduced into evidence in the criminal trial above referred to, and identified by Martin A. Clemens as having been received and read by him in 1947. This Exhibit indicates defendants were warned two years ago as to the dangers inherent in the indiscriminate sale of these drugs to the public without a physician's prescription.

(5) Defendants are in the midst of unloading a large quantity of these drugs without prescription upon the public. Defendants are thereby now causing immediate and irreparable injury, loss, and damage to the public for the reasons stated in the medical affidavits which accompany this affidavit.

/s/ ROBERT S. ROE,
Chief, Los Angeles District, Food and Drug Administration.

Subscribed and sworn to before me, this 2nd day of September, 1949.

EDMUND L. SMITH,
Clerk, U. S. District Court, Southern District of California.

[Seal] By /s/ WM. R. WHITE,
Deputy. [21]

Exhibit A

(Copy)

Roche-Organon Inc.
Nutley 10, New Jersey
Hormones

July, 1947

Gentlemen:

One of our most popular dealer helps is our literature imprinting service. Demands for Roche-Organon literature bearing the name and address of the individual dealer have increased by leaps and bounds. Because of the growing popularity of this service and because a number of dealers have only recently become Roche-Organon distributors, we would like to repeat and reemphasize the salient points of this service.

As you know, it is the firm policy of Roche-Organon never to advertise its products to the laity; therefore, the literature which you request and receive is for distribution only to your physicians. In fact, all of the more recent Roche-Organon literature bears this legend: "This pamphlet has been prepared for dissemination to the medical profession exclusively."

All Roche-Organon products, with the exception of Cytora, are strictly prescription items; literature, therefore, must be kept out of the hands of your customers. You would be breaking faith with your physicians to do otherwise. In fact, you might even endanger lives, for hormones are powerful therapeutic agents which must be administered under strict medical supervision.

So pass along these facts to all your clerks: (1) Roche-Organon literature is for physicians only. (2) Keep Roche-Organon literature out of reach of your customers. (3) All Roche-Organon products (except Cytora) bear an Rx legend on their labels, and therefore may be dispensed only on a physician's prescription. (4) Don't give out literature with prescriptions for Roche-Organon products even when the patient asks for it.

Strict observance of these rules means that the professional standing of your store will rise. Your physicians will regard your store as a truly professional hormone headquarters.

Sincerely yours,

ROCHE-ORGANON INC.

NAL-GF
(Copy)

[Endorsed]: Filed September 2, 1949. [22]

[Title of District Court and Cause No. 10266-PH.]

ORDER GRANTING TEMPORARY RESTRAINING ORDER

Plaintiff having filed a Complaint for a temporary restraining order without notice, for a preliminary injunction, and for a permanent injunction; and plaintiff having filed affidavits in support of the prayer for a temporary restraining order without notice; and the Court having con-

sidered the Complaint and supporting affidavits; and it appearing that the defendants will continue to violate the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 331(a) and (k)] unless restrained by order of this Court; and it appearing that the defendants are causing immediate and irreparable injury and damage to the public through its present and threatened distribution of hormone products in violation of the Federal Food, Drug, and Cosmetic Act since these drugs may cause sterility in men, may accelerate the growth of cancer in the prostate gland in men, may accelerate the growth of cancer of the breast, cervix, and uterus in women, and may do injury to the [17] female generative system; and it appearing that the giving of notice to the defendants would unduly delay protecting the public from these dangerous drugs;

It Is Therefore Ordered that the plaintiff's prayer for a temporary restraining order without notice be and is hereby granted, and that the defendants, El-O-Pathic Pharmacy and Martin A. Clemens, and their officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with all or any one or more of them, be and they are hereby temporarily enjoined and restrained from directly or indirectly causing the introduction or delivery for introduction into interstate commerce, in any form or manner, of any methyl testosterone linguets, or any methyl testosterone tablets, or any alpha-estradiol preparations, which are misbranded as follows:

(1) 5-milligram methyl testosterone linguets whose labeling suggests that they are effective in the treatment of male hormone deficiency when one tablet is administered daily.

(2) 5-milligram or 10-milligram methyl testosterone linguets, or 10-milligram or 25-milligram methyl testosterone tablets, whose labeling fails to state all of the disease conditions for which they are offered to the public, particularly rejuvenation of sexual potency in men.

(3) 5-milligram or 10-milligram methyl testosterone linguets, or 10-milligram or 25-milligram methyl testosterone tablets, whose labeling fails to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health.

(4) 10-milligram methyl testosterone linguets, or 10-milligram or 25-milligram methyl testosterone tablets, which are dangerous to health when taken in accordance with the directions on their labeling.

(5) Alpha-estradiol preparations whose labeling fails to state all of the disease conditions for which they are offered to the public, particularly to alleviate disease conditions related to change of life in women.

(6) Alpha-estradiol preparations whose labeling fails to bear adequate warnings against use in those pathological conditions where their use [18] may be dangerous to health.

(7) Alpha-estradiol preparations which are dan-

gerous to health when taken in accordance with the directions on their labeling.

It Is Further Ordered that said defendants and all other persons hereinabove enumerated be and they are hereby temporarily enjoined and restrained from directly or indirectly causing any act to be done with respect to the articles of drug, hereinabove described, while said drugs are held for sale after shipment in interstate commerce, which results in said drugs being labeled as above prohibited.

Unless otherwise ordered by this Court, this order shall expire at 4:30 p.m., September 6, 1949.

Dated this 2nd day of September, 1949.

/s/ JACOB WEINBERGER,
U. S. District Judge.

[Endorsed]: Filed September 2, 1949. [19]

[Title of District Court and Cause No. 10266-PH.]

ORDER TO SHOW CAUSE

Upon the Complaint and affidavits annexed hereto, and in view of the issuance by this Court of an Order Granting a Temporary Restraining Order on this date, it is this 2nd day of September, 1949, by the United States District Court for the Southern District of California, Central Division,

Ordered that the defendants, El-O-Pathic Pharmacy and Martin A. Clemens, show cause before

this Court in Dept. 3 at 10 a.m. on the 6th day of September, 1949, or as soon thereafter as counsel can be heard, why a preliminary injunction should not issue in this cause as prayed for in said Complaint; provided that copies of this Order and of the said Complaint and affidavits be served on said defendants forthwith but not later than on the 5th day of September, 1949.

/s/ JACOB WEINBERGER,
United States District Judge.

[Endorsed]: Filed September 2, 1949. [23]

[Title of District Court and Cause No. 10266-PH.]

AMENDMENT TO COMPLAINT FOR INJUNCTION

United States of America, plaintiff herein, by and through James M. Carter, United States Attorney for the Southern District of California, respectfully amends the Complaint for Injunction, heretofore filed in this proceeding, as follows, no responsive pleading to the original Complaint having as yet been served by the defendants:

(1) The caption of the Complaint is changed to add Vita Pharmacals, Inc., a corporation, as a defendant.

(2) Paragraph 2 of the Complaint, page 1, is changed to read as follows:

The defendants, El-O-Pathic Pharmacy, Inc.,

and Vita Pharmacals, Inc., are corporations having their principal place of business at 1109½ No. Western Avenue, Hollywood, California. The defendant, Martin A. Clemens, is the manager of both said corporations, and is primarily responsible for their policies and [25] activities.

(3) Delete paragraph 8(a) on page 4 of the Complaint, lines 6-11; delete paragraph 10(b) on page 5 of the Complaint, lines 16-21; and substitute the following paragraph in the place of each of these deleted paragraphs:

Within the meaning of section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] in that the labeling of said linguets fails to bear adequate directions for use in all conditions for which said linguets are prescribed, recommended, and suggested in their labeling and their advertising matter disseminated and sponsored by the defendants.

(4) The following paragraphs are added to page 6 of the Complaint, after line 21:

13(a). Defendants also cause to be introduced into interstate commerce a drug consisting of methyl testosterone combined with Vitamin B_1 in linguet form. Said drug is labeled as follows:

COPY OF CARTON LABEL

[Front Panel]

180 Tablets

Male Hormone (Methyl Testosterone)
Combined with Vitamin B_1

Here

Directions: For use by adult males mildly deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms. Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B_1 (Thiamin Hydrochloride) in a specially [26] prepared base for sublingual use.

(See instructions on back of box)

Maywood Pharmacal Company

[Back Panel]

Double-Your-Money-Back Agreement

If you use Maywood Hormones as directed and are not fully satisfied with the results you have obtained, return the box and the unused tablets to Maywood Pharmacal Company and we will cheerfully give you double your money back.

Suggested Dosage: One light tablet upon arising before breakfast, and one dark tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve

slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician.

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician. [27]

[Top Panel]

Maywood Hormones

The hormones in this package are of purest laboratory-controlled potency. Maywood Hormones may be obtained in 30, 60 and 180-tablet packages.

Maywood Pharmacal Company

[Side Panel]

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.

[Bottom Panel]

Methyl Testosterone
combined with Vitamin B_1

Maywood
Distributed by Maywood Pharmacal Company
6912 Hollywood Blvd.
Hollywood 28, Calif.

[Side Panel]

Pull out cellophane tape and tear off individual "Pocket Pak" at perforation. Each pocket contains average daily dose of one light (morning) and one dark (evening) tablet. This special package keeps your hormones sanitary and permits you to carry your daily dosage conveniently in your pocket. Tear off corner of pack to extract morning tablet, then cellophane can be folded to protect evening tablet until taken. [28]

13(b). The aforesaid drug (methyl testosterone combined with Vitamin B_1), labeled as described in paragraph 13(a), violates section 301(a) of the Act [21 U.S.C. 331(a)] in the following respects when defendants cause it to be introduced into interstate commerce:

(1) Within the meaning of section 502(a) of the Act [21 U.S.C. 352(a)] in that the labeling is false and misleading, since it represents and suggests that the suggested daily dosage is efficacious for use in the treatment of male hormone deficiency, whereas the sug-

gested daily dosage would be entirely ineffective for that purpose;

(2) Within the meaning of section 502(f)-(1) of the Act [21 U.S.C. 352(f)(1)] in that the labeling of said linguets fails to bear adequate directions for use in all conditions for which said linguets are prescribed, recommended, and suggested in their labeling and advertising matter disseminated and sponsored by the defendants.

(3) Within the meaning of section 502(f)-(2) of the Act [21 U.S.C. 352(f)(2)] in that the labeling of said linguets fails to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling is couched is inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of cancer of the prostate gland or may cause sterility.

/s/ JAMES M. CARTER,
United States Attorney.

Affidavit of Service by Mail attached.

[Endorsed]: Filed September 20, 1949. [29]

[Title of District Court and Cause No. 10266-PH.]

CONSENT AND ORDER

It Is Hereby Stipulated by and between the plaintiff, United States of America, and the defendants, El-O-Pathic Pharmacy and Martin A. Clemens and Vita Pharmacals, Inc., through their respective counsel, that hearing on the Order to Show Cause, heretofore set for 10 a.m., on September 26, 1949, in this proceeding, be continued to 10 a.m., on October 3, 1949, or the first available date subsequent thereto, and that the Temporary Restraining Order issued by this Court on September 2, 1949, in this proceeding, shall be and remain in full force and effect until this Court rules on the plaintiff's prayer for a preliminary injunction after the hearing on said Order to Show Cause.

Dated: September 26, 1949.

JAMES M. CARTER,
United States Attorney,

CLYDE C. DOWNING,
Assistant United States Attorney,

/s/ GEORGE E. DANIELSON,
Assistant United States Attorney, Attorneys for Plaintiff.

/s/ EUGENE M. ELSON,
Attorney for Defendants.

It Is So Ordered this 30th day of September, 1949.

/s/ PEIRSON M. HALL,
United States District Judge.

[Endorsed]: Filed October 3, 1949. [31]

[Title of District Court and Cause No. 10266-PH.]

ANSWER OF DEFENDANT MARTIN A. CLEMENS, AN INDIVIDUAL, AND VITA PHARMACALS, INC., A CORPORATION.

Defendants Martin A. Clemens, individually, and Vita Pharmacals, Inc., a corporation, by way of answer to the Complaint for Injunction filed herein and the Amendment thereto, admit, deny and allege as follows:

I.

Answering the allegations of Paragraph 2 of said Complaint, as amended, said defendants alleged that El-O-Pathic Pharmacy, Inc., sued herein as a co-defendant and a corporation, was dissolved as a corporation on or about September 7th, 1949; that dissolution proceedings were instituted on or about August 19th, 1949, and that said El-O-Pathic Pharmacy, Inc., is no longer in existence, and that all of the assets and liabilities of said corporation were purchased by defendant Vita Pharmacals, Inc., a corporation, on or about the 22nd day of August, 1949, and that [32] Vita Pharmacals, Inc., a corporation, is now and at all times since on or about August 19th, 1949, has been a corporation organ-

ized and existing under the laws of the State of California. In this connection, these answering defendants allege that defendant Martin A. Clemens is neither a director, officer or stockholder of defendant Vita Pharmacals, Inc., a corporation, but is now and at all times since on or about the date of its incorporation has been the General Manager thereof and primarily responsible for the policies and activities of said corporation, subject to the approval or disapproval of the Board of Directors thereof.

II.

Answering the allegations of Paragraph 3 of said Complaint, defendants deny that defendant Martin A. Clemens is now or at any time since on or about July 13th, 1949, has been a distributor of male or female hormone drugs as described in Paragraph 3 of said Complaint except in his capacity as General Manager aforesaid of Vita Pharmacals, Inc., a corporation, since on or about August 19th, 1949.

III.

Answering the allegations of Paragraph 4 of said Complaint, defendants admit that the male and female hormone drugs referred to in Paragraph 3 of said Complaint, to wit: methyl testosterone tablets (10-mg. and 25-mg.); methyl testosterone in linguet form (5-mg. and 10-mg.); and female hormone drugs consisting of various preparations containing alpha-estradiol (ranging from .01-mg. to .5-mg.) are manufactured by Ciba Pharmaceutical Products, Inc., of Summit, New Jersey; by Roche-

Organon, Inc., of Nutley, New Jersey; and by Shering Corporation, of Bloomfield, New Jersey; and are shipped in interstate commerce by said manufacturers to Vita Pharmacals, Inc., a corporation. Admit that during the interstate and intrastate journeys of said drugs from said manufacturers to defendant Vita Pharmacals, Inc., a [33] corporation, the labeling of each of said drugs bears the legend: "Caution: to be dispensed only by or on the prescription of a physician."

IV.

Answering the allegations of Paragraph 5 of said Complaint, defendants admit that defendant Vita Pharmacals, Inc., a corporation, and defendant Clemens, as General Manager thereof, do not require a physician's prescription; admit that defendant Vita Pharmacals, Inc., a corporation, and defendant Clemens as General Manager thereof, have, since on or about the date of incorporation of defendant Vita Pharmacals, Inc., re-packaged and re-labeled said drugs and have offered for sale, both interstate and intrastate, male hormone drugs without requiring a physician's prescription. These answering defendants deny that they have re-packaged and re-labeled said drugs and offered all of said drugs for sale without a physician's prescription as alleged in said Paragraph 5 of said Complaint, and in this connection defendants allege as follows: that from July 13th, 1949, to on or about August 19th, 1949, defendant Clemens did not sell or offer for sale in interstate commerce any of the

aforesaid drugs; that commencing on or about August 19th, 1949, as General Manager of defendant Vita Pharmacals, Inc., a corporation, said defendant Clemens and said defendant Vita Pharmacals, Inc., a corporation, did sell and offer for sale in interstate commerce, until restrained by this Court, the aforesaid male hormone drugs without requiring a physician's prescription, but said defendants have not, nor have either of them, at any time or at all since July 13th, 1949, sold, offered for sale, distributed or delivered for introduction into interstate commerce, any of the aforesaid female hormone preparations. Defendants allege that any and all male hormone drugs sold, offered for sale, distributed or delivered for introduction into interstate commerce by them or [34] either of them at any time since on or about August 19th, 1949, have been re-labeled by affixing to the container in which said drugs and each of them have been sold, offered for sale, distributed or delivered for introduction into interstate commerce, a label, a true and correct replica of which is attached hereto and marked Exhibit "A" hereto. Defendants further allege that no other labeling of any kind or character than that represented by Exhibit "A" hereto has been attached to any of said male hormone drugs, nor has any labeling other than that represented by Exhibit "A" hereto accompanied the shipment of any of said male hormone drugs in interstate commerce since on or about August 19th, 1949.

V.

Answering the allegations of Paragraph 6 of said Complaint, defendants and each of them deny generally and specifically each and every allegation contained therein.

VI.

Answering the allegations of Paragraph 7 of said Complaint, defendants admit that former customers of El-O-Pathic Pharmacy, a corporation, and former customers of Health Chemicals Co., have been circularized, offering methyl testosterone linguets in quantities up to 1000 to be purchased before the mail order department of said El-O-Pathic Pharmacy and said Health Chemicals Co. is discontinued on September 15th, 1949, and in this connection defendants allege that defendant Vita Pharmacals, Inc., a corporation, purchased from Health Chemicals Co. its mailing list of customers, and that the mailing list of the customers of El-O-Pathic Pharmacy, a corporation, was among the assets sold and transferred by said El-O-Pathic Pharmacy, a corporation, to defendant Vita Pharmacals, Inc., a corporation, on or about August 19th, 1949, and that the purpose of so circularizing former customers of El-O-Pathic Pharmacy and Health Chemicals Co. by [35] defendant Vita Pharmacals, Inc., a corporation, was to retain the customers of said organizations represented by the respective mailing lists thereof as customers of said defendant Vita Pharmacals, Inc., a corporation. A true and correct copy of the circular so addressed to former customers of El-O-Pathic Pharmacy, a corporation,

is attached hereto and marked Exhibit "B." A true and correct copy of the circular so addressed to former customers of Health Chemicals Co. is attached hereto and marked Exhibit "C."

VII.

Answering the allegations of Paragraph 8 of said Complaint, as amended, these answering defendants deny generally and specifically each and every allegation contained therein.

VIII.

Answering the allegations of Paragraph 9 of said Complaint, these answering defendants deny generally and specifically each and every allegation contained therein.

IX.

Answering the allegations of Paragraph 10 of said Complaint, these answering defendants deny generally and specifically each and every allegation contained therein.

X.

Answering the allegations of Paragraph 11 of said Complaint, these answering defendants deny generally and specifically each and every allegation contained therein.

XI.

Answering the allegations of Paragraph 12 of said Complaint, these answering Defendants admit that defendant Vita Pharmacals, Inc., a corporation, and defendant Clemens as General Manager thereof, have, since on or about August 19th, 1949,

sold the said methyl testosterone tablets and methyl testosterone linguets freely in intrastate and interstate commerce without a physician's prescription but labeled in the manner aforesaid. [36] Deny generally and specifically each and every other allegation contained in said Paragraph.

XII.

Answering the allegations of Paragraph 13 of said Complaint, these answering defendants deny generally and specifically each and every allegation contained therein.

XIII.

Answering the allegations of Paragraph 13(a) of said Complaint, as amended, defendants admit that defendant Vita Pharmacals, Inc., a corporation, and defendant Clemens as General Manager thereof, have caused to be introduced into interstate commerce a drug consisting of methyl testosterone combined with Vitamin B_1 in linguet form, and that said drug so introduced has been and is labeled in the manner and form described in said Paragraph 13(a). Said defendants attach hereto and mark as Exhibit "D," a true, correct and actual label so affixed to said product.

XIV.

Answering the allegations of Paragraph 13(b) of said Complaint, as amended, these answering defendants deny generally and specifically each and every allegation contained therein.

nothing by its action, and for such other and further relief as may be proper.

HOWLET AND ELSON,

By /s/ EUGENE M. ELSON,
Attorneys for Defendants.

44-A

Exhibit A

VITA HORMONES 100 Tablets

Each Tablet Contains 5 Mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by VITA PHARMACALS, INC.
1109½ No. Western Ave. Hollywood 27, Calif.
HOllywood 9-1722

(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

VITA HORMONES 100 Tablets

Each Tablet Contains 10 Mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by VITA PHARMACALS, INC.
1109½ No. Western Ave. Hollywood 27, Calif.
HOllywood 9-1722

(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

VITA HORMONES 100 Tablets

Each Tablet Contains [redacted] Methyl Testosterone 25mg

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by VITA PHARMACALS, INC.
1109½ No. Western Ave. Hollywood 27, Calif.
HOllywood 9-1722

(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

EXHIBIT "A"

Exhibit B

Special Bulletin

Dear Customer:

We are very sorry to inform you that effective September 15, 1949, the Mail Order Department of the El-O-Pathic Pharmacy will be discontinued.

We sincerely hope this notice will give you ample time to place your order for as many of our tablets as you may need for future use. Since many of our customers will be ordering in large quantities, we would suggest that you place your order without delay.

Please bear in mind that your order must be received and shipped on or before September 15, 1949, as this is absolutely the last date that shipments will be made.

We would like to take this opportunity to thank you for your past orders and for a very pleasant business relationship.

Sincerely yours,

EL-O-PATHIC PHARMACY,
1109½ No. Western Ave.,
Hollywood 27, Calif.

Health Chemicals Co.
c/o El-O-Pathic Pharmacy,
1109½ North Western Ave.
Hollywood 27, Calif.

Price List of Male Hormones
Methyl Testosterone
Regular Strength Linguets

☐ 30 Tablets $5.00
☐ 100 Tablets $13.00
☐ 250 Tablets $29.00
☐ 500 Tablets $55.00
☐ 1000 Tablets (Hospital Size) $95.00

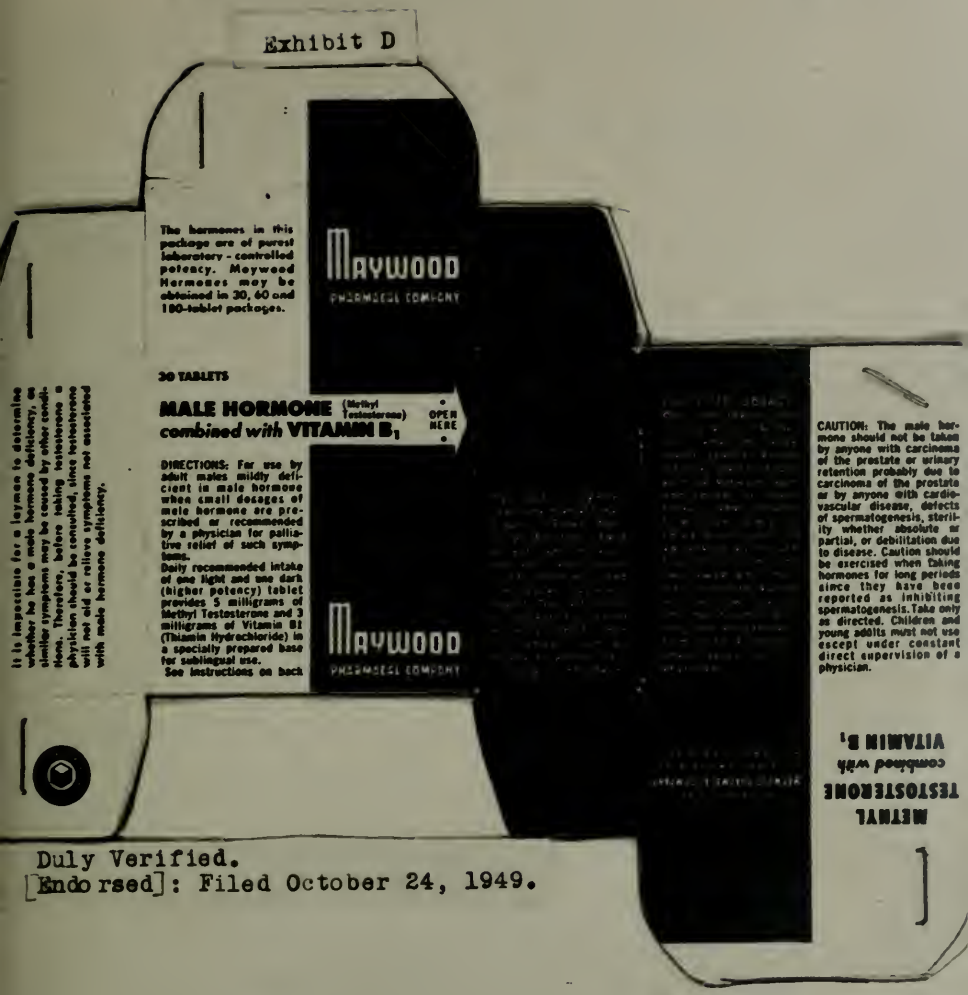
Name .....
Address .....
City ..... State .....

Please print name and address

☐ Cash ☐ C.O.D. ☐ Check or Money Order

48-A

Exhibit D



Duly Verified.
[Endo rsed]: Filed October 24, 1949.

EXHIBIT "D"

(Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF EUGENE M. ELSON

State of California,
County of Los Angeles—ss.

Eugene M. Elson, being duly sworn, deposes and says:

That he is an attorney-at-law licensed to practice in all of the Courts of the State of California and before the above-entitled Court. That he was the trial counsel for the defendants in the criminal action referred to in the Affidavit of Martin A. Clemens filed herein. During said trial some gentleman whose name affiant does not recall sat at the end of the counsel table with the Government counsel advising and assisting them during the course of said trial. Your affiant spoke with this gentleman during several intermissions and he advised your affiant that he was a doctor of medicine employed by the Food and Drug Administration in [45] Washington, and that his activities and practice were devoted to the field of endocrinology. Your affiant stated to him in substance as follows:

> "Isn't it a fact that regardless of the labeling these people might devise for the sale of methyl testosterone without prescription, the Food and Drug Administration would never approve it?"

and said individual replied, in substance,

> "That is right. We would never approve any

labeling for over the counter sales of methyl testosterone because it is our purpose to see that it is sold only on prescription."

On October 17, 1949, your affiant requested and obtained from the Clerk of the above-entitled Court the file in the case of U. S. vs. Walter Kurt Max Hassenstein, No. 19,004, Criminal. At said time your affiant examined all the documents in said file and copied therefrom certain portions of the documents contained therein. Your affiant alleges that the defendant in said action was prosecuted by information charging him with a violation of Sections 352(f)(1) and 352(f)(2) of the U. S. Code, the corresponding sections of which in the Federal Food, Drug and Cosmetic Act are Sections 502(f)-(1) and 502(f)(2). Hereinafter in this affidavit reference to the aforesaid Federal Food, Drug and Cosmetic Act will be made instead of reference to Sections of the U. S. Code. In said information it was charged that the labeling attached to and accompanying the product involved in said action violated the aforesaid sections. Said information quoted said labeling as follows:

"Rx 5000

"Important

"To be used as directed by physician. Not to be used by children or when pregnant or [46] in the presence of serious diseases like diabetes, tuberculosis, cancer or when abnominal pains (stomach-ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of

appendicitis are present. Ampules should not be used in cases of nephritis, myocarditis and arteriosclerosis and threatened rupture of the uterus. Frequent or continued use of this preparation may result in dependence on laxatives. * * *"

It was charged in said information that Section 502(f)(1) of said action was violated by the aforesaid label in that it failed to reveal the reason for using said article of drug. It was further charged that Section 502(f)(2) of said action was violated in that said "drug contained a solution of Posterior Pituitary and the statement, to wit, 'should not be used in cases of nephritis, myocarditis and arteriosclerosis' in the labeling was not adequate to warn against use of the drug in kidney disease, heart disease and hardening of the arteries; and in that the labeling of said drug bore no warning against use by persons with high blood pressure."

A Motion to Dismiss said information was filed on behalf of the defendant and in support thereof a Memorandum of Points and Authorities was filed. In opposition to the Points of Authorities of said defendant the Government filed a Memorandum of Points and Authorities. On page 2, line 20, to page 3, line 12, of the said Memorandum it was stated:

"With respect to the alleged misbranding in violation of Section 352(f)(1) (Section 502(f)-(1), Federal Food, Drug and Cosmetic Act) defendant rests his Motion to Dismiss upon the contention that nothing in that Section of the

Act requires the labeler to reveal the reason for the use of [47] the article, particularly since the labeling contained the statement that the preparation was to be 'used as directed by physician.' Plainly, if it is required that the labeling set forth the reasons or conditions for which the drug is to be used, such requirement is not fulfilled by a statement that it is to be used as directed by a physician. Moreover, such a direction is ambiguous and provides no assurance that the purchaser will consult a member of the medical profession. The regulations promulgated under Section 352(f)(1) (502(f)(1), Federal Food, Drug and Cosmetic Act) provide for an exemption of the requirement that the labeling contain adequate directions for use if, among other things, the labeling of the drug bears the statement 'Caution: To be dispensed by or on the prescription of a physician [21 Fed. Reg. (Cum. Supp.) Section 2.106(b)(4)].' Defendant has not taken advantage of this exemption but, rather, has carefully avoided it. Compliance with the requirements of the exemption would assure the direction and guidance of a physician in the use of the drug. The statement, however, placed on the drug by defendant does not, as stated, give any such assurance. Thus, the situation presented is apparently one where the drug is so dangerous in its use that the advice of a physician is ambiguously suggested, but the language

which would insure the drug's use on the instruction of a [48] physician is absent."

The said Memorandum of the Government further continued at considerable length on the theme that Section 502(f)(1) of said Act requires the labeling on a drug to state the conditions under which it is to be used. It was further contended in said Memorandum of the Government that the warning on the labeling used works unknown and "mysterious" to the average user.

In reply to said Memorandum of the Government the defendant filed a Memorandum of Points and Authorities contending that Sections 502(f)(1) and 502(f)(2) of the Act do not require "the purpose for the use of the medical preparation should be shown on the label," and on page 2, lines 1-5, further stated:

> "When there is taken into consideration also the fact that the pleading sets forth that the product is to be used 'as directed by physician,' there can be no intimation that the statement was not inserted as a warning against the use of the product except as designated by the physician * * *."

Also in said Memorandum of the defendant it was stated on page 2, lines 22 to 29, as follows:

> "The matter of describing cases of 'nephritis, myocarditis and arteriosclerosis' and the allegation that these diseases should be described as 'kidney, heart disease and hardening of the arteries, respectively, has no precedence in our

law. It would cause a criminal act to arise if, in the whimsy or caprice of a Government official the identical words approved by the Government official were not used, * * *"

Thereafter, the above-entitled Court rendered its opinion [49] entered in the Minutes of said Court as follows:

"Hall, J.:

"The statement on the label 'Important. To be used as directed by physician,' is in my judgment an 'adequate direction' for the use of the product. It is not to be used at all unless a physician directs it. To put more on the label would be to suggest it could be used without the direction of a physician which would be more apt to be false and misleading than the simple statement as used.

"The words 'nephritis, myocarditis, and arteriosclerosis' are dictionary words which are commonly understood to mean certain types of kidney, heart or arterial diseases. The warning that the product should not be used in such cases appearing under the word Important together with the statement, 'To be used as directed by physician,' is an 'adequate warning' sufficient to comply with the statute as to all except children, and is not false or misleading.

"As to the 'adequate warning against its use by children' I do not know how a more adequate warning could be given on a label

(b) Particulars Wherein Misbranding than the statement 'not to be used by children.'

"The motion to dismiss is granted."

/s/ EUGENE M. ELSON.

Subscribed and sworn to before me this 21st day of October, 1949.

[Seal] /s/ JAMES C. HYNE,
Notary Public in and for Said County and State.

[Endorsed]: Filed October 24, 1949. [50]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF MARTIN A. CLEMENS

State of California,
County of Los Angeles—ss.

Martin A. Clemens, being duly sworn, deposes and says:

That he makes this Affidavit in response to certain of the allegations contained in the Complaint for Injunction and Amendment thereto and the Affidavits of Robert S. Roe, Clinton Hobart Thienes, M.D.; Elmer Belt, M.D., and Ian MacDonald, M.D., all on file in the above-entitled proceeding.

That on or about March 22nd, 1949, there was filed an Information in the above-entitled Court numbered 20596, in which affiant Clemens was named as a defendant. In said Information it was charged that defendant Clemens delivered for in-

troduction into interstate commerce certain male hormone drugs and that the same were misbranded in violation of the Federal Food, Drug and [51] Cosmetic Act. The product involved in each Count of said Information involving male hormone drugs, the particulars wherein said products were therein alleged to be misbranded, together with the Sections of the Federal Food, Drug and Cosmetic Act alleged to have been violated, were as follows:

Count I.

(a) Product:

methyl testosterone tablets, 25-mg. each; oral dosage: 1 to 2 tablets daily;

(b) Particulars Wherein Misbranding Was Alleged:

That accompanying said product in interstate commerce was a circular entitled "Male and Female Sex Hormones." Affiant attaches hereto and marks Exhibit "A" to this Affidavit a copy of the circular which accompanied said product.

(c) Violation Charged:

1. Section 502(a), Food, Drug and Cosmetic Act: That the labeling represented and suggested that said product
   a. would stimulate growth and development of the sex organs;
   b. would stimulate growth and development of the male sex characteristics, such as
      (1) distribution of hair
      (2) muscular development
      (3) depth of voice

c. would correct lack of sexual power and impotence;
d. would relieve and postpone the many conditions associated with middle age;
e. would improve the sense of well-being; [52]
f. constituted an adequate treatment for
   (1) flushes
   (2) sweats
   (3) chills
   (4) impaired memory
   (5) inability to concentrate on activities and tendency to evade them
   (6) nervousness
   (7) general weakness and lack of physical strength

That the labeling represented and suggested that

a. The use of said drug would result in improved physical and mental work
b. The use of said drug would exert a tonic action resulting in renewed vigor
c. Said drug would impart a better attitude toward social life
d. Said drug would cause nervousness, exhaustion and melancholy to disappear in the average man in his late 40's

That said representations and suggestions were false and misleading in that

a. Said drug would not accomplish the aforesaid purposes

2. Section 502(f)(2), Food, Drug and Cosmetic Act:

That said drug was further misbranded in that

a. The said labeling failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, in that each tablet of said drug [53] containing 25-mg. of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

3. Section 502(j), Food, Drug and Cosmetic Act: That said drug was further misbranded in that

a. it was dangerous to health when used in the dosage and with the frequency prescribed, recommended ad suggested in its labeling, since each tablet of said drug contained 25-mg. of male hormone (methyl testosterone) and the use of a drug containing 25-mg. of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit: as directed on the box labeling: "1-2 tablets daily," and as directed in the aforesaid circular: "1 tablet a day," would be dangerous to health since such use of said drug may result in sterility and such use by individuals with early and

incipient carcinoma of the prostate may result in acceleration of the malignant growth.

Count II.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding Was Alleged:

Same as in Count I [54]

(c) Violation Charged:

Same as in Count I

Count IV.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding Was Alleged:

Same as in Count I

(c) Violation Charged:

Same as in Count I except that there was no charge of failure to bear adequate warnings against use in certain conditions, etc., in violation of Section 502-(f)(2) of said Act.

There was a charge made under this Count (violation of Section 301(k) of said Act) which is not material here.

Count V.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding Was Alleged:

Accompanying literature: it was not alleged that the circular referred to in the previous Counts, Exhibit "A" hereto, accompanied this product. The position of the government was that no literature other than the label on the immediate container of the product accompanied the shipment.

(c) Violation Charged:

1. Section 502(j), Food, Drug and Cosmetic Act, as in Count I. [55]

Count VI.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding Was Alleged:

Same as in Count I

(c) Violation Charged:

1. Section 502(a), Food, Drug and Cosmetic Act, as in Count I.

2. Section 502(j), Food, Drug and Cosmetic Act, as in Count I.

It was not charged in this Count, as in Count I, that Section 502(f)(2) of said Act was violated in failing to bear adequate warnings against use in certain pathological conditions, etc., etc.

Count VII.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding Was Alleged:

Accompanying literature: it was not charged that any literature, such as Exhibit "A" or otherwise, other than the labeling upon the immediate container in which the product was shipped accompanied this product.

(c) Violation Charged:

So far as is material here, Section 502(j), Food, Drug and Cosmetic Act, as in Count I.

Count VIII.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding Was Alleged:

Same as in Count I [56]

(c) Violation Charged:

1. Section 502(a) of said Act, as in Count I.
2. Section 502(j) of said Act, as in Count I.

A violation of Section 502(f)(2) of said Act, as in Count I, was not charged under this Count.

Count IX.

(a) Product;

Same as Count I

(b) Particulars Wherein Misbranding Was Alleged:

Accompanying literature: it was not alleged that

(c) Violation Charged:

1. Section 502(a) of said Act, as in Count I.
2. Section 502(f)(1) of said Act, as in Count I. That the labeling of said drug failed to bear adequate directions for use in that it bore no directions for use.

   However, it was alleged in said Count that said circular, Exhibit "A" hereto, did accompany said shipment and product, and affiant alleges that said circular was therefore part of the labeling.
3. Section 502(f)(2) of said Act, as in Count I.

Recapitulating the aforesaid charges insofar as the same are material to this litigation, the charges of the government were that the labeling of said products so shipped constituted a misbranding of said products for the following reasons:

1. That said labeling falsely represented and suggested that said products would be efficacious in the treatment of the conditions enumerated hereinbefore under the discussion as to Count I in violation of Section 502(a) of the Food, Drug and Cosmetic Act.

2. That said labeling failed to bear adequate warnings against use in those conditions where it might be dangerous to health in that the labeling failed to warn that its use might result in sterility and its use by individuals with early and incipient carcinoma of the prostate might result in acceleration of the malignant growth.

3. That said product was dangerous to health

in that 25-mg. thereof as prescribed: 1-2 tablets daily, [59] would be dangerous to health in the aforesaid respects in violation of Section 502(j) of said Food, Drug and Cosmetic Act.

At the outset of the trial of said action, said defendant Clemens took the position and maintained the same throughout that the symptoms referred to in said Exhibit "A" hereto would be relieved if the individual manifesting the same were suffering from a male hormone deficiency, and that said circular, Exhibit "A," did no more than make such a representation, and did not represent that said male hormone products would be efficacious in the treatment or relief of said symptoms though they might have been caused by some condition other than a male hormone deficiency, and at the outset of said action offered to the Court and served a copy thereof upon counsel, his argument in this respect entitled "Comparison of Information re Alleged Therapeutic Claims with Labeling Involved (the Pamphlet 'Male and Female Sex Hormones')," and said document so submitted became part of the files and records in said action.

Government Evidence in Support of the Aforesaid Charges

In support of the aforesaid charges, several medical witnesses were called by the government to testify. References to the reporter's transcript in said criminal action will hereinafter be made for convenience in the event that it should develop that

said reporter's transcript should be a part of the record in this case.

I.

Clinton A. Thienes, M.D.

So far as material to this case, said witness testified as follows: [60]

That in early cancer of the prostate, presence of cancerous growth may not be recognized, and that the administration under such circumstances of methyl testosterone would stimulate the cancerous growth and perhaps carry it to the point where it is no longer cureable. (R. T., p. 27) Assuming a man to be 50 years of age who complains of flushes, sweats, extreme nervousness, inability to concentrate, nocturia, and who goes to his doctor who is an average general practitioner, and no evidence of cancer of the prostate is diagnosed, he does not believe that the doctor would prescribe testosterone for a period of time and wait and see whether the symptoms were relieved. (R. T., p. 39-41) In his opinion, the general practitioner today, before prescribing testosterone, would want to be sure that his patient was suffering from the male climacteric, and in his opinion, the majority of general practitioners would require laboratory tests as to the secretion of hormones from the testes before prescribing testosterone.

The consensus of medical opinion is that methyl testosterone will cause sterility. (p. 54). Testosterone is dangerous unless prescribed "under the guidance of a physician." (p. 62).

Symptoms such as inability to concentrate and irritability in males of approximately 50 years of age are present in conditions other than hormone deficiency. Most of those symptoms are due to something other than such a deficiency. (p. 66). The only sure way that he knows to determine whether or not there is a hormone deficiency is by laboratory procedure—an analysis of the urine. (p. 67).

II.

Warren Nelson, M.D.

Professor of Anatomy and Endocrinology, University of Iowa. His studies have shown that injection of testosterone will result [61] in a lower production of spermatozoa and a lowered production of the hormones of the testes. (p. 79-80). This inhibition lasts for the duration of the treatment. How much beyond that it is difficult to say. (p. 82).

From his own research he cannot make any statement as to the effect on the testes—sterility—of methyl testosterone, but the concensus of opinion as he interprets it is that it will inhibit sperm cell production and production of testosterone by the interstitial cells. (p. 98).

He would be unwilling to say that 25-mg. of testosterone injected (this is testosterone propinate, not methyl testosterone, the latter being taken orally) would make the person sterile. In his opinion, it would reduce the production of spermatozoa and make the person less fertile. Sterility implies complete lack of fertility, (p. 102) and therefore the term

"sterility" as used in the Information, is used incorrectly. (p. 106).

If a person went to a doctor and the doctor prescribed testosterone, the result, so far as the inhibitory effect of testosterone on sperm production is concerned, would be the same as though the individual bought it at a store without prescription except that he is sure that the physician would have warned him that his fertility would probably be decreased, and if he treated himself, the patient wouldn't know that. (p. 107).

He believes that the average physician would so advise the patient. (p. 108).

In his opinion, the male climacteris is an unusual and rarely encountered condition. (p. 108). It is undoubtedly a procedure done in some instances to give a person methyl testosterone when he manifests symptoms of the male climacteric. It is assumed in those conditions that if the person is relieved, the individual is going through the male climacteric. However, at the University where individuals are admitted and are suspected of having the male [62] climacteric, laboratory tests are made to determine whether he properly belongs in that category or should receive other forms of therapy. (p. 108, 109). There is, however, a difference between the method employed by a doctor in his position associated with Universities or experimental institutions and the method in which the average general practitioner approaches the same problem. The economic factor of time as well as other factors enter into the approach. (p. 109, 110).

III.

Dr. Norris J. Heckel, M.D.

Professor of Urology, University of Illinois.

He uses testosterone in urology only for the treatment of men who have a deficiency of the male sex hormone. (p. 158). Such deficiency is found in endocrine disturbances best illustrated by eunuchism and by men who have been castrated or whose testes have been injured. (p. 159-160).

Hormone therapy would not correct impotence in a man in his late 40's unless it were due to a male hormone deficiency. (p. 168-169). In his opinion, if a man were suffering from a male hormone deficiency, methyl testosterone would correct lack of sexual power and impotence. Also, it would postpone the many conditions associated with middle age and improve the sense of well-being. If a man were suffering from a hormone deficiency, methyl testosterone would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength. (p. 172, 174). However, there are many diseases other than a male hormone deficiency that would produce those symptoms. If a man were suffering from a male hormone deficiency, methyl testosterone would result in improved physical and mental work and would exert a tonic action resulting in renewed [63] vigor and would impart a better attitude toward social life and cause nervousness, exhaustion and melancholy to disappear. How-

ever, those symptoms are also symtoms of diseases or conditions other than a male hormone deficiency. (p. 173-175).

A male hormone deficiency is first determined by a careful history, second, a careful physical examination, and third, laboratory tests to aid in the diagnosis, such as the estimation of 17 ketosteroids in the urine, and also, by the estimation of the secretion of the gonadtropins in the urine. (p. 176). There are no objective symptoms which would enable him to correctly diagnose a male hormone deficiency. (p. 177).

Methyl testosterone will aggravate a prostatic cancer. (p. 180).

As to a patient calling on a general practitioner complaining of the several symptoms enumerated, i.e., nervousness, etc., etc., in his opinion the general practitioner would make a careful examination of the patient to see if he could find out what is producing the symptoms. He would conduct a complete physical examination from head to foot. If that produced nothing, he would probably examine the urine to see whether there was any sugar in it which might give him a clue to diabetes which would produce such symptoms. If he found no sugar, he would determine whether there was any albumin in the urine or whether the patient was suffering from Bright's Disease or some kidney disturbance. If nothing turned up then, he would take the patient's blood pressure. If that were normal and his urine negative, he would probably take a blood count to

see whether the patient was suffering from anemia. There might be some indication that the patient had a gastro-intestinal disturbance, and an x-ray picture of the tract or of the colon would be taken, or a basal metabolic test to discover whether he had some disturbance of his thyroid. If such doctor found nothing suspicious as a result of such examination, [64] he might, but he shouldn't, suggest testosterone to the patient for a period of 4 to 6 weeks to see if those symptoms were relieved. (p. 186-190).

He has never been able to make a diagnosis of the male climacteric. The only way that he can explain the vast quantity of testosterone sold is that he does not know of any doctor who has presented evidence of a definite diagnosis of that condition. (p. 191).

He has never been able to learn from talking with his colleagues or to find an article written by anyone in which they tell how to make a diagnosis of the male climacteric. (p. 193). There is no question but that in view of the hundreds of thousands of packages of testosterone sold during the year, testosterone is indicative of considerable benefit to many, many, many men. (p. 194-195). He believes from his own experience that methyl testosterone accelerates the growth of an incipient carcinoma of the prostate. (p. 197-199).

He questions whether the average family doctor who found what he believed to be a male hormone deficiency and who examined the patient to see whether cancer was present, would try the man on testosterone to see whether he was relieved of his symptoms. The chances are 99 times out of 100 that

the general practitioner would find something specific as a reason for the patient's symptoms. (p. 214).

IV.

Dr. Elmer Belt

He is a urologist and a member of the Belt Urological Group. (p. 224 & 372).

He has personally seen or treated patients who have had adverse or injurious results from the administration of the male hormone. (p. 227). He thinks that very definitely the administration [65] of testosterone influenced the growth of a prostatic cancer in a doctor of medicine who was his patient and who was 48 years of age. (p. 228). Cancer of the prostate is fairly frequent in the decade between 50 and 60—is much more frequent between 60 and 70. (p. 229). He sees a very selected group of patients who come to him because they have trouble in urinating. (p. 229). In the case of the ordinary practitioner to whom a patient goes because he wants a general physical examination, the practitioner is obligated to put his finger in the rectum and carefully feel the prostate. (p. 233, 234). He is convinced that testosterone is a stimulating factor for the growth of carcinoma of the prostate. (p. 243). But, about cancer of the prostate there are many more things about it that are unknown than are known. (p. 244). There are many instances in which methyl testosterone is very valuable. The precautions necessary to its use are tests: (1) the rectal examination; another, the level of acid phosphatase in the bloodstream, and two

other tests of recent origin, one, a test of the proteins of the blood, which shows the presence of cancer or the absence of it, and another, a blood protein test. He feels that such precautions are a prerequisite to any testosterone therapy except in groups where cancer of the prostate is not liable to occur and by that he means cases in which it is particularly valuable or the group of young individuals who show a definite endocrine deficiency in regard to testosterone and who need it in the normal process of their growth and development. (p. 246, 247). By that he is referring to boys who had their testicles blown off in the war, (p. 390) and persons suffering from hypogonadism—persons whose testicles are not performing their proper function, meaning undeveloped testicles and undeveloped genitalia—a young individual whose testicles are not up to standard in size and function. (p. 391, 392).

The acid phosphatase test, if one is set up for it, can be [66] completed in a few minutes. The 17 ketosteroids test requires approximately a week to complete, and the blood test a very short time. The general practitioner is not equipped to make either of those tests and in fact, his office is not equipped to make the 17 ketosteroids test, and he is having them made at California Institute of Technology. (p. 395). In a person who is apparently normal physically, the examination necessary to determine whether he is suffering from an endocrine deficiency might possibly be the 17 ketosteroids test. (p. 248). The examinations that he has referred to require special training. There are no objective symptoms of a male

hormone deficiency which a layman could recognize and actually use to diagnose such a condition. He might confuse almost anything with the loss of what he thought was his normal quantity of hormones. (p. 249). After a careful examination of the patient and no indications of cancer of the prostate being present, it would still be dangerous or conducive to the development of cancer of the prostate for the person to take testosterone. (p. 251-253).

In his opinion, if a man 45 to 50 years of age came to a general practitioner and stated that he was troubled with sweats, nervousness, did not remember things as he used to, couldn't concentrate on activities, had a tendency to evade them, and the doctor was of the opinion, after learning of these symptoms, that testosterone might be of benefit to the patient, the general practitioner would, before prescribing testosterone, in the first place, think—think about the problem, and if he thought about it very much he probably wouldn't prescribe testosterone for those symptoms because they do not indicate hypogonadism and it is virtually only in hypogonadism that testosterone is effective. (p. 383-384). A very careful analysis of the problem would be needed for that patient and he would be very apt to get it at the hands of an alert general practitioner. (p. 385). It would be a [67] very loose method of detecting the man's trouble for the general practitioner to prescribe testosterone to such a patient for a period of 3 to 4 weeks to see whether the man has been relieved, for if the doctor really thought about the problem, got down to business and studied it, he would be concerned first

about the psychic factors in the individual and whether he was overworked and troubled. (p. 385). Before prescribing testosterone, the general practitioner would certainly make a rectal examination and feel the prostate. As to blood or urine tests, there would be no blood tests that such doctor need do, unless he wished to do the acid and alkaline phosphatase tests. The urine test would not show him anything unless he wished to take the time to give the 17 ketosteroids test. (p. 385-386). If he really wanted to find out if the man had a hormone deficiency, he would give such a test, as well as the acid phosphatase test, for cancer of the prostate, (p. 386) and if he used testosterone, then he would see that the symptoms were not relieved. (p. 387).

The problem of hormone deficiency is the specialty of the general practitioner. The middle aged man who is tired and wornout and who has come to the doctor for some help is the general practitioner's "meat." (p. 388).

In the case of the individual who comes to the general practitioner and which doctor gives him a rectal examination and finds nothing suspicious and prescribes methyl testosterone for the patient, and the patient has the prescription filled that the doctor has given him, that patient can go back to a drugstore as often as he wishes and have that prescription refilled without going to that doctor or to any other doctor and having a new prescripition made up for him each time he wants it. In fact, he doesn't have to have a prescription in the first place.

(p. 398). He can go back and have it refilled as often as he wants without even seeing another doctor. (p. 399) [68]

What he is pleading for in this case is that the requirement be made that this product, methyl testosterone, be sold only on prescription. (p. 400).

He does not think that the male has any climacteric, and he believes that most careful observers are of the same opinion. However, that is not an opinion that is universally shared by the profession. (p. 407).

If a patient comes to him referred by another doctor, he always allows the other doctor the benefit of whatever doubt might exist in his mind, and his tendency is to go on with the original treatment the other doctor has established until he can communicate with him and discuss the problem with him. (p. 436-437).

V.

Dr. Charles Huggins, M.D.

Professor of Urology, University of Chicago.

Since 1938 their work has been almost exclusively related to the male hormone and its action in normal and cancerous individuals. (p. 256-258). He does not think that a male hormone deficiency occurs in quasi-normal individuals—persons who are not hypogonads or who have been castrated. (p. 260). He denies that methyl testosterone would have any effect upon the conditions enumerated in the Information. Those symptoms are not symptoms of a person who is deficient in male hormones. (p. 272-275). Because of the toxic effects of the male hormone, he thinks that

testosterone should always be administered under the supervision of somebody with some knowledge of such matters. (p. 277). Testosterone in certain doses will certainly result in sterility to the user. (p. 279). Testosterone accelerates the growth of cancer of the prostate. (p. 281, and 286-287). As to the blood tests to determine the presence of cancer of the prostate, the ordinary practicing physician is not capable of doing such tests in his office unless he were chemically minded, but the average [69] good-sized hospital could determine it. (p. 289-291).

In his opinion, if an individual complained to a general practitioner—all around family doctor—of the symptoms referred to in the Information, some would prescribe methyl testosterone for a period of 4 to 6 weeks and see whether the symptoms were relieved without going through the elaborate tests described by him, but some doctors would not, and he thinks that very few informed physicians would prescribe it under those circumstances. (p. 292). He doesn't think that the average physician would recognize the symptoms referred to as an indication for sex hormones. The blood test he referred to can only be done in well-established hospitals. (p. 294). Listlessness, lack of memory, etc., as described in the Information, cannot be helped by the administration of male hormones even if the person were suffering from such a deficiency. He does not believe that there is such a thing as the male climacteric though there is a difference of opinion on that subject in medical circles, and there are a great many articles in which the male climacteric is discussed, but

he does not share the opinion of those investigators. (p. 303, 304). He is a professional investigator, (p. 311) and eliminating the eunuchoids, castrates and women, he does not think that they have prescribed testosterone in his hospital during the last 5 years. He disagrees with statements concerning the male climacteric by Dr. Hans Lisser and Robert F. Escamilla appearing in Volume 46 of "The Urologic and Cutaneous Review," page 87, February, 1942. (p. 313-315). He disagrees with statements of Dr. Harry Benjamin on the subject of impotence and its treatment by testosterone appearing in the "Urologic and Cutaneous Review," Volume 50, page 143, March, 1946, and with regard to the article by Dr. August A. Werner, entitled "The Male Climacteric: Additional Observations of 37 Patients," appearing in the Journal of Urology, Volume 49, page 82, June, 1943, he thinks they are [70] absurd and he is in complete disagreement with them. (p. 315-316).

Defense Evidence

So far as material to the issues before the Court in this case, the defense evidence in said criminal action was as follows:

I.

Martin A. Clemens

That he is a pharmacist licensed to practice in California and has been since 1927. That he purchased testosterone from Roche-Organon Company, Ciba Pharmaceutical Supply Company, and the Shering Corporation, and in addition thereto, received

literature from those companies. He has been selling testosterone since 1943 and no one at any time has made any complaint concerning alleged damage or injury from the use of said product. (p. 456-457). Since 1943 he has sold between four and five million tablets or about 127,000 boxes. These boxes were in sizes of 15, 30, 100, and 500 tablets to a box. (p. 458-459). About 20% of his sales comprised 15 tablets to a box. About 70% comprised 30 tablets to a box. About 10% comprised 100 to a box, and very few were sold in 500 tablets to a box. This latter size usually is used by dispensers. (p. 460). He has purchased testosterone from other drugstores up and down the State and had no difficulty in purchasing over the counter. (p. 476). In Los Angeles he has purchased it over the counter at 9 out of 10 drugstores that he called on. (p. 477).

The manufacturers from whom he purchased his supply furnished him with any quantity of literature that he wanted. (p. 487).

With reference to the Affidavit of Robert S. Roe on file herein, and the statement therein contained in Paragraph 4 thereof referring to Exhibit "A" attached to said Affidavit—the letter [71] of July, 1947, from Roche-Organon, Inc., affiant alleges that notwithstanding the contents of said letter, said Roche-Organon, Inc. continued to supply affiant with literature such as referred to in said letter. (p. 491). The agents of said company told him to ignore the letter; that it was merely put out to appease the medical profession, and they kept supplying him with that literature from then on, and said literature came

directly from the company's office in New Jersey. Said agents and contact men told affiant that they had to keep their product council-accepted with the medical profession—that they still had to have the outlet counsel, and to continue passing out and selling the product and the literature. (p. 525-527).

As to the allegations in said Affidavit of Robert S. Roe that affiant was warned two years ago by said letter as to the dangers inherent in the indiscriminate sale of said drugs to the public without a physician's prescription, affiant alleges that notwithstanding the contents of said letter, as aforesaid said company continued to supply him with methyl testosterone for sale to the public over the counter and without prescription, and that said company knew at all times that he was so selling said product and using the literature furnished by them to him in connection therewith. Furthermore, affiant alleges that respectable medical opinion was convincing to him that testosterone was not dangerous and that he was so advised by numerous physicians and surgeons. In addition thereto, affiant was convinced that it was possible for any individual to call on general practitioners at random, request a prescription for testosterone, and that the same would be provided without any semblance of a medical or other examination, and that by reason thereof the average general practitioner was not of the opinion that testosterone was dangerous and required the elaborate tests and examinations testified to by government witnesses in said criminal action, and [72] as more fully appears hereinafter in this Affidavit, a witness for affiant in

said criminal action did call upon 15 general practitioners at random, request and obtain prescriptions for testosterone without the semblance of a physical or any examination being made upon said individual. In addition thereto, as more fully appears hereinafter in this Affidavit, a witness for said affiant in said criminal action did call upon government witnesses Belt and Heckel and did obtain from said witnesses prescriptions for testosterone without any of the elaborate tests testified to by said witnesses as being necessary as a prerequisite for the administration of testosterone being conducted.

In addition thereto, at the conclusion of said criminal action, counsel for the government stated to the Court that he felt that because advertisements were run by affiant in the newspaper up to the day of judgment, a substantial penalty should be imposed, to which the Court replied that said defendant, affiant herein, had a right to assume himself innocent until the Court passed upon the question.

In addition thereto, the State Board of Pharmacy of the State of California, in March of 1948, held hearings throughout the State as to whether or not testosterone should be included in the list of dangerous drugs which could be sold only on prescription, and after said hearing said Board refused to place said drug upon said dangerous drug list, and the action of said Board in that connection is part of the Exhibits in the aforesaid criminal action. By reason of all of the aforesaid, affiant did not consider, prior to the Judgment of the Court in said criminal action,

that testosterone was dangerous in the respects alleged or otherwise. [73]

II.

Dr. George E. Fakehany, M.D.

Is a Doctor of Medicine, (p. 536) and prescribes testosterone on an average of once a day and has never encountered any adverse results from the use of it. (p. 542).

He prescribes testosterone to males complaining of the symptoms alleged in the Information of said criminal action. He usually prescribes a month's supply and tries it for a certain period of time to see whether the person is relieved of the symptoms complained of. (p. 547). Many individuals are relieved and some not. (p. 548). That is quite a usual procedure in the practice of medicine. It is common practice. (p. 548).

He does not submit such a patient to the tests referred to by the government medical witnesses. (p. 553-554). The symptoms referred to may or may not be caused by a hormone deficiency. (p. 582).

III.

Dr. Paul E. Travis, M.D.

Is a Doctor of Medicine (p. 596) and he prescribed testosterone for a person manifesting the symptoms referred to in the Information in such criminal action. (p. 598).

He does not nor does he know of any general practi-

tioner who submits such a patient to the tests referred to by the government medical witnesses, (p. 602) and he has never encountered any adverse results from the administration of testosterone. In his experience he has found males to suffer from a hormone deficiency. (p. 604).

IV.

Dr. William A. Swim, M.D.

Is a Doctor of Medicine and has practiced internal medicine [74] in Los Angeles since 1918. (p. 653). Was formerly a member of the Board of Medical Examiners of the State of California. (p. 654).

If a person complained to him of the symptoms described in the Information, he would take a general history, make a physical examination and prescribe testosterone, (p. 654) and has done so on many occasions and ever since there has been testosterone. There has been testosterone in commercial quantities for about the last 10 years. On many such occasions he has found the individual's symptoms to be relieved and has never encountered any adverse results. (p. 655). He is familiar with what is known as the male climacteric and the symtoms of a person suffering therefrom are those symptoms referred to in the Information. (p. 656). He does not in his practice submit the patient to the elaborate tests mentioned by the government witnesses. (p. 657).

V.

Allen H. Parkinson

Testified as a witness for the defense and stated

that on June 24th, 1949 (following the date on which government witness Dr. Elmer Belt testified on direct examination) he went to Dr. Belt's office on Wilshire Boulevard at 10:00 a.m. and asked to see one of the doctors, and was referred to a Dr. Ebert, and told him that he would like some testosterone. The doctor asked him if he had ever taken it before and he replied that he had two years ago in Salt Lake City. That a Dr. Openshaw prescribed some. (p. 696-697). He stated to said Dr. Ebert that he had trouble with diminishing of the testicles and penis, and the doctor asked him if he was taking it then, and he replied "no," but that he continued taking it at frequent intervals because it had a tonic effect and made him feel better. The doctor asked him if a 50-mg. shot of testosterone propinate would be satisfactory, and he replied that it would. He was then shown another room, and [75] in a moment a laboratory assistant entered and took a blood sample from him. Then Dr. Belt entered the room, inserted his finger in the witness' rectum, and another technician entered and injected him with testosterone. Said Dr. Belt asked him what he wanted on his prescription—how many tablets he wanted—and the witness replied that he would like 100 10-mg. linguets of methyl testosterone. Dr. Belt then said "all right" and asked him to urinate in three glasses, which he did, and asked him how he took them, and he replied that he took 3 or 4 a day, and then maybe laid off 3 or 4 days, depending on how he felt, and then resumed. Dr. Belt replied "all right" and "what did the doctor in Salt Lake City charge you?" and the witness replied

"$5.00" and Dr. Belt replied "All right, pay the girl $5.00 on your way out." (p. 699-700) and said Dr. Belt wrote out a prescription for 100 10-mg. linguets of methyl testosterone. (p. 700).

In addition thereto, said witness testified that on June 30th, 1949, he called at the offices of a Dr. E. A. Gummig in Pasadena (p. 701) and received a prescription for 100 tablets of methyl testosterone linguets. At no time during his visit to the doctor's office did the doctor lay any hands on him. (p. 70*io*).

At this point, your affiant alleges that said Parkinson testified as aforesaid on July 7th, 1949, and that on the following day, July 8th, 1949, the said Elmer Belt was recalled to the witness stand by the government as a rebuttal witness, and testified with reference to the visit to him of said Parkinson that he did see Parkinson on June 24th, 1949; that when he went into the room where Parkinson was, he reviewed the history which the other doctor had taken, that Parkinson told him that he had been receiving a weekly maintenance dose of 50-mg. of testosterone, and in so testifying the doctor testified from notes made in his office during the course of said examination by him and by some of his employees. (p. 825-826). Parkinson asked for a prescription of [76] 10-mg. tablets or linguets of testosterone to be taken 3 times daily. He does not think he stated that he had been taking that amount. He asked for the injection and said he was going to San Francisco and wanted to have a maintenance dose to take with him. When Dr. Belt entered the room where Parkinson was, he asked him if Dr. Openshaw referred him to

them, and Parkinson said "yes." (p. 827). That two years ago his testicles and penis had begun to atrophy and he became sexually impotent. That Dr. Openshaw of Salt Lake City had been treating him with a weekly maintenance dose of 50-mg. That he had been away from Salt Lake City for three weeks and that his physician recommended that he come to them for treatment. That he was leaving for San Francisco shortly. Belt made a complete physical of Parkinson, observed his general makeup, his eyes, his pupils, his pharynx, his teeth, felt his thyroid, examined his thorax, took his blood pressure, determined his pulse rate and rhythm, felt of his abdomen, looked at his extremities, tapped his reflexes, examined external genitalia, put a finger in his rectum and examined his prostate and as a result found no contra indications for the use of testosterone. He instructed his technician to take a specimen of his blood and he had already been instructed to urinate in three glasses which he did, and that material was examined. The reason for taking the blood sample was that Parkinson said he intended to return and the doctor wanted to know whether the acid or alkaline phosphatase had changed. (p. 828-829). Before he began his examination of Parkinson, he told him that they examined people carefully who asked for testosterone or who are getting it, to be sure it isn't doing them any harm. He did not wish to undermine Doctor Openshaw's authority as the man presented himself to him as a transient under the care of another physician, and it would have been poor taste and poor policy and poor judgment as well as poor

medicine to interfere with the activities of his [77] own physician. (p. 830).

The notes of the examination from which the doctor referred disclosed the following:

"Q. Commencing with 'Complaint,' 'Testosterone shots only.' What is that (indicating)? A. History and physical.

"Q. History and physical?

"A. Wait a minute. Past history.

"Q. What is this?

"A. H. P., past history.

"Q. Oh, H. P.

"A. I guess that is history and present ailment.

"Q. H. P. I.?

"A. History of past illness.

"Q. History of past illness. It reads as follows: Two years ago, this man's testicles and penus began to atrophy and he became sexually impotent. Dr. Openshaw of Salt Lake City has been treating him with a weekly maintenance dose of 50 milligram testosterone Neo-Hombreol. He has been away from Salt Lake City for three weeks. This physician recommended that he come here for the same shots. He will be leaving here for San Francisco shortly. Wants oral prescription for Metandren 10 milligram tablets. On the reverse side, what is this?

"A. Ear, nose and throat.

"Q. What is this up here (indicating)?

"A. Present illness, 'P. I.,' it looks ilke.

"Q. And something here. 'P. I.' the doctor

says indicates present illness. The nose, ears, eyes and throat, what is that? [78]

"A. Tonsillectomy and adenoidectomy. And then over here, 'No venereal diseases, no surgery, general health excellent; two children.' What is that (indicating)?

"A. 'Daughter, age 13—and a boy aged 6 and a girl aged 4.'

"Q. Boy aged 6 and girl aged 4. What is that (indicating)?

"A. 'Living and well.'"

(p. 832, line 4 to p. 833, line 15).

and your affiant alleges that nothing on said record of examination disclosed the results of the extended physical examination of said Parkinson which said Dr. Belt testified he had conducted.

With reference to the $5.00 fee which Parkinson had testified he was charged by Dr. Belt, said Belt explained as follows:

"A. If this patient had not been referred to me from another doctor and if this were not a routine thing, a routine procedure, we would have charged him very much more for this entire procedure. Of course, $5.00 wasn't the total charge here. We explained to him that the laboratory test would be $6.50, which he said he would like to have us bill him for to this false address that he gave us. This is a purely courtesy situation here. A patient comes in; he is being treated by another doctor in another city; we do our

best to oblige both the doctor and the patient by carrying on the procedure that the doctor feels is indicated. I asked him what Dr. Openshaw charged him for this treatment and he said $5.00. As a matter of fact, $5.00 is close to the [79] cost of 50 milligrams of testosterone propinate. I don't know exactly what the cost is to our office from the pharmacy but it is not under that. We charged him the same thing that his doctor charged him, as a matter of courtesy to that doctor, and we didn't charge him for the physical examination and for the urine analysis; nothing else except for the laboratory test." (p. 835).

VI.

Hannah Shinglman

This witness testified as a defense witness that on June 27th, 1949, she called at the Beverly Hills office of the Elmer Belt Urologic Group. (p. 739, 740). That she walked into the office and asked to see Dr. Belt and was informed by the nurse that he was not there. She then asked to see another doctor and was referred to Dr. Letourneau whose name appears on the prescription pad of the Belt Urologic Group (introduced into evidence in said case) as a member of said Group. Said doctor asked her what he could do for her and she told him that she and her husband had been in this locality 6 or 8 months and previously her husband had not been feeling well for the last few years—had been nervous, jumpy and irritable and that they figured he was going through the male

change. That a doctor in Chicago had given him some shots; that he had put him on tablets. She showed him an empty bottle which had been a container for testosterone linguets and the doctor then gave her a prescription for 100 metandren linguets, 25-mg., 1 daily, and her husband was not present at any time. (p. 745-746).

VII.

Hazen S. Parkinson

This witness testified for the defense as follows: that on Sunday, June 26th, 1949, he arrived in Chicago, and on the following [80] day called at the office of Dr. Norris J. Heckel, one of the government witnesses heretofore referred to. (p. 753-754). In a few moments the doctor came in and the witness told Dr. Heckel that he wanted to get a bottle refilled. On the label of the bottle was the language, among others: "Metandren Linguets—500." (p. 772). He showed him a prescription that he had from Dr. Openshaw for testosterone by injection, and told the doctor that he was going on a ship and wanted to take them by mouth. (p. 773). The doctor informed him that he had just returned from Los Angeles on a trial and in reply to the question from the witness "Was there anything wrong with taking them, then, that is going to do me any danger? If there is I don't want them," the doctor replied, "Oh, no, I don't know as they will do you any damage, but we don't want them sold over the counter." The doctor took a urine sample and placed his finger up the rectum of the witness, and wrote the prescription for

500 metandren methyl testosterone linguets in the witness' presence. He told the doctor he was going on a ship and that there were 3 or 4 men to a room, and every time you take a pill, someone else wants one, and he placed upon the prescription a dosage of 1 per day. About 5 or 6 minutes were consumed in this visit with the doctor. (p. 774-775). At the time of this visit the witness was 65 years of age. (p. 776).

Following this testimony, the government obtained from Dr. Heckel a letter giving his version of this visit which it was stipulated between counsel would be the testimony of said doctor if he were re-called. Said letter alleged that on June 24th, 1949, a Mr. Parkinson came to his office in Chicago and stated that he had been referred by a former patient; Parkinson said that he was 72 years of age, a sailor by occupation and gone from the country for long periods of time; that he was in Chicago as a transient; that his doctor in Salt Lake City had been giving him a prescription [81] for methyl testosterone and that he had been taking this drug under his doctor's direction for the past several years; that he was leaving the country and needed about a year's supply of testosterone and requested a prescription for a year's supply. He showed Dr. Heckel a prescription for testosterone issued by another doctor. Dr. Heckel then made a physical examination of Parkinson, which included a urine analysis and a rectal examination of the prostate and found no contraindication to the use of testosterone; he found that Parkinson's prostate was of normal size, shape and consistency, with no evidence of prostatitis; and that he then re-

newed Parkinson's prescription for methyl testosterone linguets and advised him to report to his physician at regular intervals.

During the testimony of said Parkinson, affiant herein and defendant in said action sought to elicit from said witness testimony concerning certain general practitioners called upon at random by said Parkinson during the course of said trial, from whom in each instance he obtained prescriptions for methyl testosterone without any examination being conducted. The purpose of said testimony was to dispute the testimony of government witnesses that general practitioners would not prescribe said drug without elaborate examinations to determine whether or not the individual was suffering from a male hormone deficiency or carcinoma of the prostate was indicated. Said offer of proof was refused but affiant herein alleges that he is now ready and able to prove all of the matters and things embraced in said offer of proof, and therefore alleges that said offer of proof was and is now as follows:

"I also offer to prove that Mr. Parkinson called on several doctors, on the dates mentioned on certain prescriptions, throughout parts of Los Angeles County, and talked at random; that in each instance he went into [82] the doctor's office, told the doctor that he wanted this same bottle, the one he used when he saw Dr. Heckel, refilled, and asked for a prescription; that in each instance he received a prescription for these linguets and on no occasion was anything said to Mr. Parkinson about sterility or fertility or

cancer of the prostate, nor did any of the doctors lay a hand on him, and he did not call on any doctor who turned him down on the request for a prescription.

The doctors that would be subject to Mr. Parkinson's testimony in that regard would be Dr. G. G. Ferbryck, M.D., 516 Professional Building, 117 East 8th Street, Long Beach, California, who wrote out a prescription for Metandren Linguets, one a.m. and p.m., and the date was June 29, 1949; Dr. Wayne P. Hanson, in the same building, on June 30, 1949, wrote out a prescription for 500 10-milligram Metandren Linguets, directions, one linguet daily; that he also called on Dr. George D. Stilson and Dr. Milo Ellik, together in the same office, 511 Professional Building, 117 East 8th Street, Long Beach, on June 30th, and received a prescription from Dr. Ellik for 500 Metandren Linguets, directions, as directed; that he called on Dr. Raymond W. Kelso on June 31, 1949, the doctor's address being 117 East 8th Street, Long Beach, who wrote out a prescription for 250 10-milligram Metandren Linguets, with directions, dissolve one on tongue each day; that he called on George B. Hanson, M.D., 716 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, received a prescription for 250 Metandren Linguets, 10 milligrams, directions, one per day; that he called on Dr. H. F. Gramlich on June 30, 1949, address, 117 East 8th [83] Street, Long Beach, and received a prescription for one bottle of metandren linguets, directions, as directed; that he called on Dr. P. W. Prince of the Bishop Clinic staff, 117 East 8th Street, Long Beach,

on June 30, 1949, and received a prescription for 250 10-milligram metandren linguets, directions, I guess it is, one daily, dissolve in mouth; that he called on Dr. L. L. Wiltse, 714 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 500 metandren linguets, directions, take as directed; that he called on Dr. Marvin R. Lauer, 829 East Compton Boulevard, Compton, California, on July 2, 1949, and received a prescription for 500 metandren linguets, 10 milligrams, directions, use as directed; that he called on Dr. Francis J. Ort, 107 North Santa Fe Avenue, Compton, California, on July 2, 1949, and received a prescription for 500 metandren linguets, directions, two daily; that he called on Dr. L. C. Lowe, 706 South Hill Street, Los Angeles, on July 1, 1949, and obtained a prescription for 500 metandren linguets, 10 milligrams, directions, as directed; that he called on Dr. Glenn E. Jones, 403 West 8th Street, Los Angeles, on July 1, 1949, and received a prescription for 500 metandren linguets, 10 milligrams, directions, one or two per day; that he called upon Dr. R. L. Byron, 1015 Chapman Building, 756 South Broadway, Los Angeles, on July 1, 1949, and received a prescription for 500 metandren linguets, 10 milligrams, directions, one as directed." (p. 764-767). [84]

The Re-Labeling of Said Products Subsequent to the Aforesaid Judgment of Conviction

Immediately following the judgment of conviction in said criminal action, affiant consulted with legal counsel and expert counsel in other respects on the

subject of re-labeling said product so as to conform to the objections made by the government and disclosed by government evidence in said criminal action. In so doing, affiant had in mind that said government witnesses, with the exception of Dr. Charles Huggins, had testified that methyl testosterone was of great value in relieving the symptoms referred to in the Information in said criminal case provided that the individual was suffering from a male hormone deficiency; that said symptoms might, however, be caused by conditions or diseases other than a male hormone deficiency, and that only a doctor could correctly diagnose the condition.

That it was alleged in said criminal Information that the labeling there involved failed to warn the user that said product might accelerate the growth of an incipient carcinoma of the prostate and might cause sterility. Affiant alleges that in said criminal Information the term "carcinoma of the prostate" was employed as distinguished from "cancer of the prostate." Therefore, in order to meet the objections so made by the government in said criminal action to the labeling formerly employed by affiant, he discarded all of the labeling formerly employed by him, and with the assistance of counsel as aforesaid, entirely re-drafted the labeling for said product. In order to eliminate the objections that said product should not be continued over a period of time unless under the supervision of a physician in that sterility might be caused thereby, or a carcinoma of the prostate might be accelerated in growth thereby, said affiant caused to be placed upon said label, among

other things, [85] language to the effect that said product should be taken, 1 tablet upon arising before breakfast, or 1 tablet shortly before retiring, and that "the maintenance dosage can be extended from 3 to 6 months under supervision of a physician." (Emphasis added).

In order to overcome the objections made by the government in said criminal action that an individual layman could not diagnose his need for said product, affiant caused also to be placed upon said label directions as follows:

> "For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician, for palliative relief of such symptoms." (Emphasis added).

As a further caution to users of said product that a physician should be consulted for the purpose of determining whether or not the symptoms manifested were the result of a male hormone deficiency, affiant caused to be added to said label the following language:

> "It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted since testosterone will not aid or relieve symptoms not associated with male hormone deficiency."

During the course of said criminal action, some witnesses for the government testified that should

testosterone be taken by young men who were desirous of stimulating their sexual desire it might result harmfully to them unless under the guidance of a physician. Therefore, in order to meet said objections, affiant caused to be placed upon said label the following:

> "Children and young adults must not use except under constant direct supervision of a physician." (Emphasis added). [86]

In order to meet the objections of the government and the testimony of witnesses produced by the government in said criminal action against the sale of said product without adequate warnings against the use thereof when carcinoma of the prostate is indicated and without adequate warnings that the use of said product might cause sterility, affiant caused to be placed on said label the following cautionary language:

> "The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate, or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. (Emphasis added.)

A true and correct copy of each of the labels appearing upon all of said products sold and distributed by defendants herein since the date of the judgment

in said criminal action is attached hereto and marked Exhibit "B."

In response to the allegations contained in the Complaint for Injunction in this action and the Affidavits filed in support thereof, that 5-mg. of methyl testosterone have no therapeutic value, affiant alleges that the United States Pharmacopoeia lists the dosage of methyl testosterone as follows:

"Average dose, sublingual, 5 milligrams."

That the American Medical Association, in the 14th Edition of "Useful Drugs, 1947" lists under methyl testosterone the following:

"Dosage: average dose, sublingual, 5 milligrams." That also, the American Medical Association, in its publication [87] entitled "Epitome of the Pharmacopoeia of the United States" and the "National Formulary, 8th Edition," list under methyl testosterone the following:

> "Sublingual, 5 milligrams. Methyl testosterone usually available in tablets containing these amounts."

Therefore, your affiant alleges that the re-labeling of said products as represented by the Exhibits attached hereto, complies in all respects with the particulars in which the former labeling was alleged to be deficient in said criminal action, and that said re-labeling was done in good faith and under expert counsel and advice.

Your affiant further alleges that he is informed and believes and therefore alleges that the State law of California does not, nor does the Federal law,

require that methyl testosterone in linguet or tablet form be sold only by prescription of a physician. That notwithstanding said fact, the said Food and Drug Administration of the United States government will not approve any labeling of such product for sale without prescription regardless of the warnings that may be placed thereon and regardless of the fact that said labeling may, as the labeling involved herein does, repeatedly advise the user against the use of said product except under the supervision of a physician.

In answer to the allegations of Paragraph 6 of said Complaint, affiant alleges that shortly following the judgment in said criminal action, there remained certain window and store displays which had been there prior to the institution of said criminal action. That following said judgment, said window and store displays remained for a short period of time because of the press of business imposed upon affiant in attempting to organize said business in a manner that would comply with the evidence and the judgment in said criminal action, but that said window and [88] store displays have all been taken down and eliminated and none existed in the place of business of any of the defendants in this action at the time of the filing of the Complaint herein.

Affiant denies that he, or any of the defendants, since said judgment of conviction, have represented in any newspaper advertising that said drugs would be efficacious in alleviating a variety of disease conditions or those relating to sexual impotence in man and a change of life in women, and in this connection

affiant attaches hereto and marks as Exhibit "C" a true and correct copy of the only advertisements which have appeared in any newspapers since the date of said judgment.

With respect to the allegation contained in Paragraph 3 of said Complaint as amended, that the labeling of said product fails to bear adequate directions for use in all conditions for which said product is prescribed, recommended and suggested, affiant alleges that if such a position be tenable, then it would be impossible for any drugs to be sold to the laity or except upon prescription, and your affiant is informed and believes and therefore alleges in this connection that should this drug or any other drug be so labeled as to all possible conditions for which the same might be used, that said Federal Food and Drug Administration would consider such labeling as misleading and arbitrarily institute action therefor, criminal or civil.

/s/ MARTIN A. CLEMENS.

Subscribed and sworn to before me this 14th day of October, 1949.

[Seal] /s/ EUGENE M. ELSON,
Notary Public in and for
Said County and State. [89]

MALE

and

FEMALE

SEX HORMONES

SPECIAL MALE HORMONES

FOR LIMITED TIME ONLY

50 DAY SUPPLY $5.00

100 DAY SUPPLY $9.00

REGULAR STRENGTH LINGUETS

Add 3% sales tax on mail orders

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Endocrine preparations of unusual quality for Male and Female

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MALE HORMONE
TESTOSTERONE

This discovery of the MALE SEX HORMONE is one of the achievements of modern medicine on which the public is comparatively uninformed. *Yet it is truly a tremendous accomplishment.*

PROF. RUZICKA, a Swiss chemist, succeeded in making TESTOSTERONE, "the most potent male hormone" by synthetic means; and for this he received THE

★ 1939 NOBEL PRIZE IN CHEMISTRY

"Science is unlocking the secrets of Male and Female sex hormones. Years of scientific effort and research have established that these hormones accomplish many things which up to a few years ago were thought to be impossible. These discoveries are far-reaching and assisting millions of men and women to lead happier lives, and are relieving and postponing the many conditions associated with middle age."

★ THE SEX HORMONES

All hormones play a major part in the sexual maturity of the hormonal system. The male hormone stimulates growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development, depth of voice and the impression of a sense of well-being.

★ MALE HORMONE DEFICIENCY

The average man in his late forties begins to enter what is called the "climacteric" period during which time the body undergoes a radical change. Although most of these changes may start during middle age, they may also show up at almost any time during middle age. As a rule there may be flushes, sweats and chills. Lack of sexual power, impaired memory, irritability, inability to concentrate on activities or a tendency to evade them, nervousness, depression, general weakness and poor physical strength are some of the major signs which are associated with this declining period.

★ IMPOTENCE

Lack of sexual desire and inability to perform the sexual act is one of the most common complaints of the male "climacteric." When due to a deficiency of the male sex hormone, these conditions usually respond promptly to male hormone therapy, which assist in restoring sexual desire and ability to fulfill it. In addition to re-establishing potency, the male sex hormone helps to relieve other conditions which frequently occur during this period.

★ RESULTS FROM MALE HOMONE

These social, sexual, physical and mental conditions may be overcome by the use of the male sex hormones, which often bring about startling changes. At first, it may be noticed there is a marked improvement in physical and mental work and a tonic action resulting in renewed vigor. A better attitude towards business and social life is frequently observed. Nervousness, exhaustion and melancholy gradually disappear and in the large majority of instances the improvement persists over a long period of time.

Just One Tablet a Day Swallowed, and Eliminate Unnecessary Injections

NEW 25 mg TABLET

30 Tablets	$10.00 Plus 3% Sales Tax
100 Tablets	29.95 Plus 3% Sales Tax
200 Tablets	57.50 Plus 3% Sales Tax

NO PRESCRIPTION REQUIRED

PRICES ON TESTOSTERONE FOR INJECTION BY REQUEST

MALE HORMONE

TESTOSTERONE

LINGUETS . . . under the tongue or behind the cheek

when Oral Male Hormone Therapy is Indicated

are effective in doses ½ to ⅔ the amount required when methyltestosterone is ingested. Greater economy, convenience and ease of administration mark Metandren Linguets as one of the great advances in androgenic therapy.

THE MOST ECONOMICAL ORAL ANDROGEN

The sublingual administration of methyltestosterone in the form of Linguets is based on direct venous drainage from the oral mucous membranes. The androgen is carried in the blood by the systemic venous system to the right heart, thence through the pulmonary circulation back to the left heart and thus is first distributed by the general circulation to all organs and tissues. By this route methyltestosterone by-passes the liver and escapes partial inactivation. Consequently, complete dosage is delivered to the tissues more rapidly and without loss.

NEW TABLET
Adopted March, 1948
Reg. U.S. Pat. Off.
MORE POTENT
6 tablets equals one 25 mg. injection

DOUBLE STRENGTH

Box 50 Tablets Linguets	**$ 9.50 plus 3% sales tax**
Box 100 Tablets Linguets	**17.00 plus 3% sales tax**
Box 200 Tablets Linguets	**32.00 plus 3% sales tax**
Box 500 Tablets Linguets	**75.00 plus 3% sales tax**

NO PRESCRIPTION REQUIRED

Many Excellent Reports for the Non Professional layman have already appeared in the following publications:

United States Phar.—April, 1947.
Readers Digest by Paul de Kruif, July, 1944—August, 1946.
Newsweek, March, 1943.
Time, May 28, 1945.
Newsweek, May 28, 1945.
Liberty, February 2, 1946.
True, February, 1945.

*Paul de Kruif's sensational book, "The Male Hormone," Harcourt-Brace.

*Send $1.00 plus 15c for mailing.

INFORMATION AND PRICES ON AMPULES OR VIALS SENT BY REQUEST

FEMALE HORMONE

104

A-ESTRADIOL

The estrogenic hormone promotes the development of sex characteristics in the female.

It maintains the normal condition of these characteristics in the normal adult woman.

a-Estradiol preparations confer a definite "sense of well-being."

a-Estradiol offers clinically important advantages.

a-Estradiol is the genuine hormone of the ovarian follicle, which is "probably the most potent of all known estrogens."

a-Estradiol has a smooth, dependable action which speedily controls the symptoms of ovarian deficiency and produces a gratifying sense of well-being. *a*-Estradiol is not likely to provoke side reactions or after-effects, such as headache, dizziness and gastrointestinal disturbances, which frequently complicate the action of artificial estrogens. Because of their high potency, oral *a*-estradiol tablets may be used in place of parenteral therapy in most cases. The elimination of frequent injections means not only more comfort and convenience for the patient—it also saves the physician both time and energy.

The especial therapeutic value of *a*-estradiol preparations, particularly as compared with estrone (theelin) and estriol (theelol), is today widely appreciated, since the latter two appear to be secondary products of minor importance.

THE CHANGE OF LIFE

Although this period which occurs between the fourth and fifth decades of life may pass with hardly any complaints, in many women it may cause disorders which may interfere seriously with normal living. These disorders may be mild or severe, depending upon the individual. Headache, insomnia and dizziness are frequently complained of. In severe cases, there may be fear, crying spells sometimes accompanied by melancholy and emotional instability.

PRICES—*A*-ESTRADIOL TABLETS

30 Days Supply ..... **$10.00 Plus 3% Sales Tax**
60 Days Supply ..... **17.50 Plus 3% Sales Tax**

BREAST DEVELOPMENT

DIRECT ACTION ON THE MAMMARY GLAND

Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth and the result is "definite breast growth of considerable degree." Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hypomastia presents a valuable addition to the physician's therapeutic resources.

25 Days Supply (50,000 International Units) ..... **$ 7.50**
25 Days Supply (125,000 International Units) **14.00**
50 Days Supply (250,000 International Units) **25.00**

} Plus 3% Sales Tax

NO PRESCRIPTION REQUIRED

VITA HORMONES 100 Tablets

Each Tablet Contains 5 Mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by VITA PHARMACALS, INC.
1109½ No. Western Ave. Hollywood 27, Calif.
HOllywood 9-1722

(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

VITA HORMONES 100 Tablets

Each Tablet Contains 10 Mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

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VITA HORMONES 100 Tablets

Each Tablet Contains [redacted] Methyl Testosterone 25mg

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

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(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

EXHIBIT "B"

Exhibit C

Endorsed: Filed October 24, 1949.

EXHIBIT "C"

[Title of District Court and Cause No. 10266-PH.]

SUPPLEMENTAL AFFIDAVIT OF MARTIN A. CLEMENS

State of California,
County of Los Angeles—ss.

Martin A. Clemens, being duly sworn, deposes and says:

That on or about October 14, 1949, he purchased from one of the Thrifty Drug Stores in Los Angeles three bottles each of Dr. Pierce's Favorite Prescription, Dr. Pierce's Golden Medical Discovery, Dr. Miles' Nervine and Lydia E. Pinkham's Vegetable Compound.

That the carton in which one of said bottles of Dr. Pierce's Favorite Prescription was contained is attached hereto, incorporated herein as though fully set forth and marked Exhibit "A." That enclosed within said carton was a pamphlet which your affiant attaches hereto, incorporates herein as though fully set [96] forth and marks Exhibit "B."

That the carton in which one of said bottles of Dr. Pierce's Golden Medical Discovery was contained is attached hereto, incorporated herein as though fully set forth and marked Exhibit "C." That there was no pamphlet or other literature enclosed within said carton.

That the carton within which one of said bottles of Lydia E. Pinkham's Vegetable Compound was contained is attached hereto, incorporated herein as though fully set forth and marked Exhibit "D."

That inside of said carton was a circular or pamphlet which is attached hereto, incorporated herein as though fully set forth and marked Exhibit "E."

That the carton in which one of said bottles of Dr. Miles' Nervine was contained is attached hereto, incorporated herein as though fully set forth and marked Exhibit "F." That within said carton of Dr. Miles' Nervine was a pamphlet or circular attached hereto, incorporated herein as though fully set forth and marked Exhibit "G."

/s/ MARTIN A. CLEMENS.

Subscribed and sworn to before me this 21 day of October, 1949.

[Seal] /s/ EUGENE M. ELSER,
Notary Public in and for
Said County and State. [97]

13 FLUID OZS PRICE $1.35

Exhibit A

109

Dr. Pierce's FAVORITE Prescription

FP

REG. U. S. PAT. OFF.

ACTIVE INGREDIENTS

BLUE COHOSH ROOT	(Caulophyllum Thalictroides)
BLACK COHOSH ROOT	(Cimicifuga Racemosa)
OREGON GRAPE ROOT	(Berberis Aquifolium)
BLACK HAW	(Viburnum Prunifolium)
VALERIAN ROOT	(Valeriana Officinalis)
FALSE UNICORN ROOT	(Helonias Dioica)

NO ALCOHOL

DIRECTIONS: Take 2 teaspoonfuls with water 3 times a day, preferably before or after meals.

FOR WOMEN

Of Value in Relieving PERIODIC PAINS and Associated NERVOUSNESS BACKACHE and HEADACHE*

Due to Functional Menstrual Disturbances

Dr. Pierce's Favorite Prescription was formulated by an outstanding doctor, especially for women. When taken for a time, it is of value in relieving periodic pains and associated nervousness, backache and headache* due to functional menstrual disturbances. At the same time it aids the digestion of food. This helps build women up—helps make them stronger, with more resistance.

•

*If these symptoms are due to any organic cause

13 FLUID OZS. PRICE $1.35

Dr. Pierce's FAVORITE Prescription

FP

REG. U. S. PAT. OFF.

ACTIVE INGREDIENTS

BLUE COHOSH ROOT (Caulophyllum Thalictroides)
BLACK COHOSH ROOT (Cimicifuga Racemosa)
OREGON GRAPE ROOT (Berberis Aquifolium)
BLACK HAW (Viburnum Prunifolium)
VALERIAN ROOT (Valeriana Officinalis)
FALSE UNICORN ROOT (Helonias Dioica)

NO ALCOHOL

DIRECTIONS: Take 2 teaspoonfuls with water 3 times a day, preferably before or after meals.

FOR WOMEN

Of Value in Relieving PERIODIC PAINS and Associated NERVOUSNESS BACKACHE and HEADACHE*

Due to Functional Menstrual Disturbances

Dr. Pierce's Favorite Prescription was formulated by an outstanding doctor, especially for women. When taken for a time, it is of value in relieving periodic pains and associated nervousness, backache and headache* due to functional menstrual disturbances. At the same time it aids the digestion of food. This helps build women up—helps make them stronger, with more resistance.

•

*If these symptoms are due to any organic cause

-3-

EXHIBIT "A"

Exhibit B

For Women—Of Value in Relieving

PERIODIC PAINS and Associated NERVOUSNESS, BACKACHE and HEADACHE*

Due to Functional Menstrual Disturbances

● Dr. Pierce's Favorite Prescription was formulated by an outstanding doctor, especially for women. When taken for a time, it is of value in relieving periodic pains and associated nervousness, backache and headache* due to functional menstrual disturbances. At the same time it aids the digestion of food. This helps build women up helps make them stronger, with more resistance.

*If these symptoms are due to any organic cause (abnormalities discoverable by x-ray, physical examination, or laboratory tests), you should consult your doctor.

99

ACTIVE INGREDIENTS of Dr. Pierce's FAVORITE PRESCRIPTION

Blue Cohosh Root (Caulophyllum Thalictroides)
Black Cohosh Root (Cimicifuga Racemosa)
Oregon Grape Root (Berberis Aquifolium)
Black Haw (Viburnum Prunifolium)
Valerian Root (Valeriana Officinalis)
False Unicorn Root (Helonias Dioica)

Contains no alcohol or any harmful drug.

You can get Dr. Pierce's Favorite Prescription at your drug store.

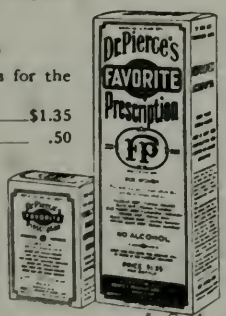
PRICES

Handy Tablets for the Purse . . .
Economy Size ____$1.35
Medium Size ____ .50

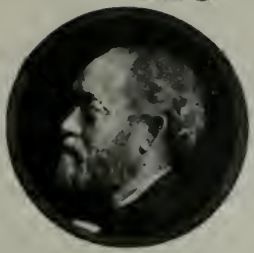
LIQUID

Economy Size $1.35

Medium Size $1.00



101



HOW Dr. PIERCE *Developed* FAVORITE PRESCRIPTION

After completing his medical training, Dr. R. V. Pierce practiced medicine in western Pennsylvania, where he soon became widely known. Among the medicines he developed in his practice were two—Dr. Pierce's Favorite Prescription and Dr. Pierce's Golden Medical Discovery. Having found these prescriptions highly successful in his private practice, Dr. Pierce moved to Buffalo, N. Y., and founded a medical company to make his medicines available to everyone. Here he also founded a hospital that became famous throughout the country. Today, over 75 years after Dr. Pierce formulated his Favorite Prescription, it is continuing to grow in favor.

100

DIRECTIONS for using Dr. Pierce's FAVORITE PRESCRIPTION

Take 2 teaspoonfuls or 2 tablets with water 3 times a day, preferably before or after meals.

Take the medicine regularly and faithfully, so that it has time to bring you the benefits you seek. If no improvement is noted within a reasonable time, consult your physician.

CAUTION: Cap the bottle when putting it away after each dose. If you are using the liquid medicine, shake the bottle thoroughly each time before using.

NOTE TO DIABETICS: 8 teaspoons of the liquid Favorite Prescription are equivalent to 4 teaspoonfuls of sugar. The tablets have only a little sugar in their coating.

102

FOR PEOPLE WHO ARE

OCCASIONALLY CONSTIPATED

Recommended for

BOTH ADULTS AND CHILDREN

● If you occasionally have a dull headache suffer from loss of appetite or feel sluggish and tired because of constipation—we believe you will find Dr. Pierce's Pleasant Purgative Pellets a most effective and pleasant laxative.

These pellets are very mild in action. Yet are highly effective in aiding nature to eliminate waste in the bowels. Very important, Dr. Pierce's Pleasant Purgative Pellets are so small (actually not much larger than the head of a pin) that they are easy to swallow. Even children as young as 8 years find them pleasant to take. You can get Dr. Pierce's Pleasant Purgative Pellets from your druggist.

Only 30c at any drug store.

Dr. Pierce's

PLEASANT PELLETS

103

We Recommend Dr. Pierce's

GOLDEN MEDICAL DISCOVERY

In Cases of

GAS PAINS, HEART BURN and Other Symptoms of COMMON INDIGESTION

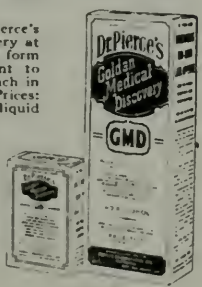
*When the Cause is Not Organic**

In such cases, Dr. Pierce's Golden Medical Discovery contains ingredients which promote more normal stomach and intestinal activity, so helping to digest food better and more thoroughly and over a period of time make gas pains and discomforts of indigestion less likely.

You can get Dr. Pierce's Golden Medical Discovery at your drug store in liquid form or in tablets convenient to carry to work or to lunch in your pocket or purse. Prices: Tablets $1.35 and 50c; liquid $1.35 and $1.00.

If gas pains and indigestion persist, see your physician.

*These symptoms may be due to a number of other conditions. If you have any doubt regarding the cause of your symptoms, you should consult a doctor.



111

People May Be

THIN, RUN-DOWN and TIRE EASILY

Due to No Organic Cause*

But Due to Poor Appetite or Poor Digestion

If you are underweight, tire easily, and are run-down due to no organic cause—while your symptoms may be due to a number of other conditions—the answer may be simply this:

First, you may not have sufficient appetite to eat enough food; and, equally important, you may not be digesting your food properly.

Dr. Pierce's Golden Medical Discovery may help both ways. It contains ingredients which stimulate the appetite –helps make you really hungry—promotes more normal stomach and intestinal activity—and this, over a period of time, helps you digest and assimilate food in order to turn strength-building elements into energy, vitality, and added flesh.

*Organic cause means abnormalities discoverable only by x-ray, physical examination, or laboratory tests.

104

A Diuretic and Analgesic to Promote the Flow of Urine and Relieve Muscular Pain!

MANY PEOPLE SUFFER from the discomfort of scanty and over-frequent urination. They may have to get up several times at night, so that normal rest is disturbed. The scanty urine is concentrated; it may be acid and, hence, burn. Muscular pains may also be associated with this condition.

WHEN THESE SYMPTOMS are not due to any organic cause, Dr. Pierce's A-Nuric tablets are of value as a diuretic to promote the flow of urine and as an analgesic to relieve muscular pain.

THE URINE BECOMES less concentrated, alkaline instead of acid. Thus the painful acid irritation of the membrane should be gently relieved. The urge to over-frequent urination should be reduced. Hence sleep is less likely to be interrupted. And, because of their analgesic properties, Dr. Pierce's A-Nuric tablets should relieve muscular pains.

You can get Dr. Pierce's A-Nuric Tablets at your drug store.

Package of 100 tablets . . . 65c

Dr. Pierce's

A-NURIC

F1-3 1047

104

Exhibit C

112

We Recommend

Dr. Pierce's Golden Medical Discovery

In cases of

GAS PAINS, HEARTBURN

and other symptoms

of COMMON INDIGESTION

When the Cause is not Organic*

In such cases Dr. Pierce's Golden Medical Discovery contains ingredients which promote more normal stomach and intestinal activity so helping to digest food better and more thoroughly and over a period of time make gas pains and discomforts of indigestion less likely.

If gas pains and indigestion persist, see your physician.

•

13 FLUID OZS. PRICE $1.50

Dr. Pierce's Golden Medical Discovery

GMD

REG. U S PAT OFF

ACTIVE INGREDIENTS

OREGON GRAPE ROOT	(Berberis Aquifolium)
CASCARA BARK	(Rhamnus Purshiana)
QUEEN'S ROOT	(Stillingia Sylvatica)
WILD CHERRY BARK	(Prunus Virginiana)
GENTIAN ROOT	(Gentiana Lutea)
STONE ROOT	(Collinsonia Canadensis)
BLOOD ROOT	(Sanguinaria Canadensis)

NO ALCOHOL

DIRECTIONS: ADULTS: Take 1 teaspoonful with water 4 times a day, preferably one-half hour before meals and before retiring at night. After one week increase this dosage to 2 teaspoonfuls 4 times a day.

FOR CHILDREN: (6 to 12 years old) ½ to 1 adult dose, (12 to 18 years old) 1 to 3 4 adult dose.

People may be

THIN, RUN-DOWN and TIRE EASILY

Due to no Organic Cause* but due to Poor Appetite or Poor Digestion

---

If you are underweight, tire easily and are run down due to no organic cause—while your symptoms may be due to a number of other conditions—the answer may be simply this:

First you may not have sufficient appetite to eat enough food and equally important, you may not be digesting your food properly.

Dr. Pierce's Golden Medical Discovery may help both ways. It contains ingredients which stimulate the appetite—helps make you really hungry—promotes more normal stomach and intestinal activity—and this over a period of time helps you digest and assimilate food in order to turn strength-building elements into energy, vitality and added flesh.

13 FLUID OZS. PRICE $1.50

Dr. Pierce's Golden Medical Discovery

GMD

REG. U S PAT OFF

ACTIVE INGREDIENTS

OREGON GRAPE ROOT (Berberis Aquifolium)
CASCARA BARK (Rhamnus Purshiana)
QUEEN'S ROOT (Stillingia Sylvatica)
WILD CHERRY BARK (Prunus Virginiana)
GENTIAN ROOT (Gentiana Lutea)
STONE ROOT (Collinsonia Canadensis)
BLOOD ROOT (Sanguinaria Canadensis)

NO ALCOHOL

DIRECTIONS: ADULTS: Take 1 teaspoonful with water 4 times a day, preferably one-half hour before meals and before retiring at night. After one week increase this dosage to 2 teaspoonfuls 4 times a day.

FOR CHILDREN: (6 to 12 years old) ½ to 1 adult dose, (12 to 18 years old) 1 to 3 4 adult dose.

-5-

EXHIBIT "C"

WITH VITAMIN B_1
(THIAMIN)

15% Alcohol used solely as a solvent and preservative. This Compound contains Vitamin B_1 (Thiamin), Gentian, Black Cohosh, True & False Unicorn, Life Root Plant, Dandelion, Chamomile, Pleurisy Root.

When taken according to directions, this product supplies 333 U.S.P. Units (1 milligram) of Vitamin B_1 (Thiamin) per day, representing the normal minimum daily requirement.

Prepared by
LYDIA E. PINKHAM MEDICINE COMPANY
Lynn, Massachusetts, U.S.A.

For relieving certain symptoms associated with and caused by the Menopause (Change of Life) and as a uterine sedative in Painful Menstruation — when not due to organic disease. For particulars, see folder inside.

Directions:

One tablespoonful four times a day, before meals and at bedtime. Take Regularly throughout the month. Shake bottle well before using.

LYDIA E. PINKHAM'S
VEGETABLE
COMPOUND
Lydia E. Pinkham

WITH VITAMIN B_1
(THIAMIN)

15% Alcohol used solely as a solvent and preservative. This Compound contains Vitamin B_1 (Thiamin), Gentian, Black Cohosh, True & False Unicorn, Life Root Plant, Dandelion, Chamomile, Pleurisy Root.

When taken according to directions, this product supplies 333 U.S.P. Units (1 milligram) of Vitamin B_1 (Thiamin) per day, representing the normal minimum daily requirement.

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Directions:

One tablespoonful four times a day, before meals and at bedtime. Take Regularly throughout the month. Shake bottle well before using.

kit.

Gift

A SEWING KIT

that will fit in your handbag

A handy Sewing Kit will be sent you as a reward. All you need to do is to answer these few simple questions. Be sure to enclose carton top!

1. *Where did you buy this product?*

_____
(name of store)

2. *Date when you bought it*
3. *How much did you pay for it?*
4. *Is this the first bottle of the product you have used?*

Name _____

Street Address _____

Town _____ *County* _____

State _____

We do not diagnose or prescribe or answer questions of a medical nature. Please do not ask us to do so.

Lydia E Pinkham Medicine Company

LYNN, MASS.

17714-349-600-M

BE SURE TO ENCLOSE CARTON TOP!

TEAR ON DOTTED LINE

VEGETABLE COMPOUND

For relieving certain symptoms associated with and caused by the Menopause (Change of Life) and as a uterine sedative in Painful Menstruation — when not due to organic disease.

Lydia E. Pinkham's Vegetable Compound is one of the most famous medicines ever made for girls and women to relieve certain distressing symptoms associated with and caused by Painful Menstruation and Change of Life, when not due to organic disease. For almost a century, thousands upon thousands of women have reported such benefit. Scientific clinical tests have strongly supported this efficacy of Pinkham's Compound. There are no opiates—no habit-forming or harmful ingredients in Pinkham's Compound. Instead, it contains nature's own roots and herbs plus Vitamin B_1. Lydia E. Pinkham's Compound is what is known as a uterine sedative, and tends to have a soothing, pain-relieving effect in dysmenorrhea. It is also an excellent stomachic tonic.

For a more particular statement of its benefits, turn the page.

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Lydia E. Pinkham's Compound is recommended to relieve distress when not due to organic disease...

...IN PAINFUL MENSTRUATION:

In carefully conducted medical tests, most of the women studied received marked benefit, through relief of the distress from Painful Menstruation such as cramps, headache and backache. For over eighty years, the testimonials to the record and performance of Pinkham's Compound in relieving these functional menstrual disturbances have been impressive. So if you suffer distress from such a cause, why not give Pinkham's Compound a fair trial?

Pinkham's Compound often gives temporary relief from nervous, tired, irritable, 'dragged down' feelings, when due to functional dysmenorrhea. See if Pinkham's Compound is not the 'friend' you need to make such 'difficult days' more pleasant.

DIRECTIONS: One tablespoonful 4 times a day before meals and at bedtime. Take regularly throughout the month. *Note:* Pinkham's Compound helps build up *resistance* against such distress. Clinical tests showed greater relief obtained by those who took the Compound for more than two months. But naturally, relief must not be expected in all cases. If organic disease is present, a doctor should be consulted.

...IN CHANGE OF LIFE:

The Menopause (Change of Life) has generally been considered a great handicap to the happiness of middle-aged women (usually from 38 to 52 years of age). Many women suffer from 'hot flushes' and feel highstrung, restless and nervous at this time.

In scientific tests, Lydia E. Pinkham's Compound was shown to be of marked benefit to most of the women studied, in relieving distressing symptoms associated with and caused by the Menopause. In these medical tests 'hot flushes' were remarkably reduced, and the majority of women reported definite improvement in their sense of well-being. In most of the patients, the depression and moody feelings, often present during and caused by the Menopause, were greatly relieved.

Naturally, relief must not be expected in all cases or where trouble is due to organic disease. But if you are troubled by distressing symptoms commonly associated with Change of Life, why not try Pinkham's Compound?

DIRECTIONS: One tablespoonful 4 times a day—before meals and at bedtime. To be taken over a period of months. If expected relief is not obtained, a physician should be consulted.

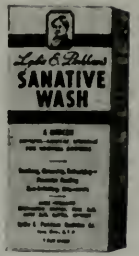
Lydia E. Pinkham's TABLETS

Girls and women! The loss of blood during monthly periods may result in a deficiency in blood-iron, which is commonly known as simple anemia. For this reason you may feel pale, weak and "dragged out." In such cases, Lydia E. Pinkham's Tablets are an effective blood-iron tonic, to help build up and fortify red blood cells. They also have a stomachic tonic effect. Easy to take—easy to carry while traveling or away from home.

DIRECTIONS: Two tablets 4 times a day, before meals and at bedtime. Take regularly throughout the month.

Lydia E. Pinkham's SANATIVE WASH

(For vaginal douches)



SANATIVE WASH is very effective in removing the discharge of LEUCORRHEA (commonly known as "the whites").
When used as directed SANATIVE WASH is 1. Antiseptic-germicidal 2. Cleansing 3. Deodorizing 4. Soothing. Safe to tissues. It relieves the discomforts of minor irritations, itching and burning. It promotes healing. SANATIVE WASH contains no harsh alkalies, phenols or mercury salts. It does not disturb the normal acidity which the vagina should have.

DIRECTIONS: Add two teaspoonfuls of SANATIVE WASH to each quart of warm water and mix well. Use as a vaginal douche in routine hygiene by means of a good fountain syringe.

Phenrin (to relieve simple headaches, muscular aches, pains accompanying colds and neuralgia)

Lydia E. Pinkham's Pills for Constipation


NET CONTENTS: 1½ FLUID OUNCES
Exhibit F
MILES
NERVINE
MILES
NERVINE
NET CONTENTS: 1½ FLUID OUNCES
MILES
NERVINE
MILES
NERVINE
ACTIVE INGREDIENTS
Each Teaspoonful (¼ oz.) Contains:
Potassium Bromide 4½ gr.
Ammonium Bromide ½ gr.
(Non-Alcoholic)
A Sedative
For the Following Functional Nervous Disturbances: Nervous Headache, Nervous Irritability and Excitability, Sleeplessness and Restlessness
ADULT DOSE:
CAUTION:
Bromides have been used for many years in the treatment of functional nervous disturbances. Miles Nervine supplies Bromides in a well balanced palatable, easily administered form.
ACTIVE INGREDIENTS
Each Teaspoonful (¼ oz.) Contains:
Sodium Bromide 4½ gr.
Potassium Bromide 4½ gr.
Ammonium Bromide ½ gr.
(Non-Alcoholic)
A Sedative
For the Following Functional Nervous Disturbances: Nervous Headache, Nervous Irritability and Excitability, Sleeplessness and Restlessness
ADULT DOSE:
CAUTION:
Bromides have been used for many years in the treatment of functional nervous disturbances. Miles Nervine supplies Bromides in a well balanced palatable, easily administered form.
MILES LABORATORIES, INC.
PRICE 25 CENTS
MILES LABORATORIES, INC.
PRICE 25 CENTS

EXHIBIT "F"

MILES
NERVINE
(Liquid)

ACTIVE INGREDIENTS

Each Teaspoonful (⅛ oz.) Contains:

Sodium Bromide	**4½ gr.**
Potassium Bromide	**4½ gr.**
Ammonium Bromide	**½ gr.**

(Non-Alcoholic)

INDICATIONS AND DOSAGE

Miles Nervine Liquid is effective as a sedative for the following *Functional ervous Disturbances:*

LEEPLESSNESS AND RESTLESSNESS

Insomnia or wakefulness at night can often be attributed to nervous or emo- onal excitability. One of the desirable effects of the active ingredients in Miles ervine Liquid is to relieve insomnia by helping to relax nervous tension and so abling one to fall asleep.

ERVOUS IRRITABILITY AND EXCITABILITY

For these, rest is the primary consideration. Modern strain and stress have aced a great load on our emotional machinery. Excitement prevents sensing of rvous fatigue of which irritability and excitability are symptoms. Miles Nervine iquid is effective in helping to relieve the over-wrought nervous condition re- onsible for these symptoms.

ERVOUS HEADACHE

Worry, anxiety, and overwork frequently produce an upset or disturbed rvous system which may result in irksome nervous headaches. A sedative, such Miles Nervine Liquid, will usually give soothing relief for headaches of this type. headache persists or recurs frequently, a physician should be consulted.

DULT DOSAGE

One or two teaspoonfuls in ½ glass of water. Take 1 teaspoonful in 1 hour necessary but do not exceed 3 teaspoonfuls in 24 hours.

AUTION

Use only as directed. Do not give to children. Over-dosage or habitual use, use in the presence of kidney disease may be dangerous. If skin rash appears, scontinue use. If nervous symptoms persist, see a physician.

MILES LABORATORIES, INC., Elkhart, Indiana, U.S.A.

WHAT IS MILES NERVINE?

For more than sixty years Miles Laboratories has sold Miles Liquid Nervine. Its essential ingredients are the bromides of sodium, potassium and ammonium, long used as effective nerve sedatives. Bromides alone are salty and somewhat disagreeable in taste. Their presentation in a pleasant-tasting and convenient form together with the inherent good qualities of the bromides themselves has given Miles Nervine its wide public acceptance.

Miles Liquid Nervine is put up in two sizes; a large size containing 8 fluid ounces, the smaller size containing 1½ fluid ounces.

MILES NERVINE IN AN EFFERVESCENT FORM

Miles Nervine is offered in a new convenient form, a compressed tablet consisting of the same time-tested active ingredients as Miles Liquid Nervine, combined with bicarbonate of sodium and citric acid, which dissolves in water with brisk effervescence to form a sparkling palatable solution.

For over sixty years the products of Miles Laboratories, Inc. have been sold subject to the consumer's entire satisfaction. Miles Nervine is no exception to this rule. If after trying your first package you are not satisfied, we will be glad to refund the purchase price.

EVERY SAFETY FACTOR IN PRODUCTION

The ingredients in Miles Nervine meet exacting standards of purity. Its manufacture is carefully controlled, with laboratory analysis by qualified chemists. Thus the consumer is given every safeguard and the assurance that Miles Nervine is as fine a preparation of its type as modern manufacturing can produce.

Miles Laboratories, founded in 1884, has developed consistently over the past sixty years and now occupies a building especially designed and equipped for research and manufacturing by modern methods. The plant is open to public inspection.

MILES LABORATORIES, INC., Elkhart, Indiana, U. S. A.

R438 P4118

Printed in U. S. A.

[Title of District Court and Cause No. 10266-PH.]

SUPPLEMENTAL AFFIDAVIT OF MARTIN A. CLEMENS

Affiant alleges that with respect to the allegations contained in said Complaint for Injunction that 5-mg. per day of methyl testosterone have no therapeutic value in said criminal information in which he was named as a defendant, counts 12, 13 and 14, involved methyl testosterone linguets containing 5-mg. each of methyl testosterone, but that no charge, claim or contention was made in said information or during the trial of said criminal action that 5-mg. of said product had no therapeutic value.

That in addition thereto when the witness Hazen M. Parkinson called upon the Government's witness, Dr. Norris J. Heckle, he received from said witness a prescription for 500 [116] methyl testosterone linguets, each containing 5-mg. of methyl testosterone, with directions written by said Dr. Norris J. Heckle to take one per day.

/s/ MARTIN A. CLEMENS.

Subscribed and sworn to before me this 31 day of October, 1949.

[Seal] /s/ EUGENE M. ELSER,
Notary Public in and for
Said County and State.

[Endorsed]: Filed November 1, 1949. [117]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF LEWIS A. SCHINAZI

State of California,
County of Los Angeles—ss.

Before me, Robert S. Roe, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmatations, and affidavits, personally appeared Lewis A. Schinazi, in the county and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am an inspector with the U. S. Food and Drug Administration, stationed at the Los Angeles District of the Administration, Los Angeles, California.

(2) On August 9, 1949, I purchased a carton of methyl testosterone without a prescription from the El-O-Pathic Pharmacy, 1109½ No. Western Avenue, Hollywood, California. At the time of this purchase, the representative of the El-O-Pathic Pharmacy who sold me the testosterone asked me for my name [118] and address, stating that he wished to keep me informed about new products in this field which might be of interest to me.

(3) On November 2, 1949, I received a commu-

nication through the U. S. Mail from Vita Pharmacals, 1109½ No. Western Avenue, Hollywood 27, California. This communication consisted of three circulars which are attached to this affidavit as Exhibits A, B, and C. Exhibit A is entitled "Price List of Male Hormones"; Exhibit B is entitled "Retardar"; and Exhibit C is entitled "Special Introductory Offer."

/s/ LEWIS A. SCHINAZI.

Subscribed and sworn to before me at Los Angeles, California, November 3, 1949.

/s/ ROBERT S. ROE,
Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV Effective June 30, 1940.

Exhibit A

Vita Pharmacals
1109½ North Western Ave.
Los Angeles 27, Calif.

Price List of Male Hormones
Methyl Testosterone 5 mg.

Regular Strength

☐ 50 Tablets.....$ 5.00 (Add 18c Tax)
☐ 100 Tablets.....$ 9.00 (Add 32c Tax)
☐ 500 Tablets.....$40.00 (Add $1.39 Tax)
☐ 1000 Tablets.....$75.00 (Add $2.63 Tax)

Methyl Testosterone 10 mg.
Double Strength

☐ 50 Tablets.....$ 9.50 (Add 32c Tax)
☐ 100 Tablets.....$17.00 (Add 58c Tax)
☐ 200 Tablets.....$32.00 (Add $1.10 Tax)
☐ 500 Tablets.....$75.00 (Add $2.63 Tax)

Name .....
Address .....
City..... Zone.... State.....

Please print name and address

☐ Cash ☐ C.O.D. ☐ Check or Money Order

I am an adult man, age.....

CAUTION: Take only as directed.

Exhibit B

Vita Pharmacals

1109½ No. Western Ave. Los Angeles 27, Calif.

"Retardar"

Helps Control Fast Ejaculation

Just a Few Drops Required

$1.00 Trial Size $5.00 Size

Name .....
Address .....
City..... Zone .... State.....

Please print name and address

☐ Cash ☐ C.O.D. ☐ Check or Money Order

Exhibit C

\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$

Special Introductory Offer

This Coupon is good for a 10 per cent Discount on all of our Hormone Products. Act Now and Save 10 Per Cent. Just deduct 10 per cent from our price list. Your order will be shipped immediately.

Send your order to:—

VITA PHARMACALS
1109½ N. Western Ave.
Los Angeles 27, Calif.

This Offer Expires December 31, 1949

\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$

[Endorsed]: Filed November 3, 1949. [120]

[Title of District Court and Cause No. 10266-PH.]

AMENDMENT TO THE ANSWER

As a separate Affirmative Defense Defendants allege:

I.

That for some time last past and now the Food and Drug Administration of the Federal Security Agency of the United States Government has interpreted, applied and enforced and does now interpret, apply and enforce Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act in an arbitrary, capricious and unlawful manner, wherein

and whereby defendants herein are deprived of their property and liberty without due process of law in violation of Article V of the Amendments to the Constitution of the United States in the following particulars:

That officers, agents and representatives and employees of said Food and Drug Administration of the United States [123] Government have uniformly enforced, applied and interpreted Section 502(f)(1) of said Food, Drug and Cosmetic Act to mean that the term "adequate directions for use" as used in said Section enables and empowers them to decide and determine whether a particular drug and particularly methyl testosterone sold by defendants should or should not be sold over the counter to lay-persons regardless of the statements and contents of the labeling thereon; that should said officers of said Administration determine and decide that a particular drug and particularly methyl testosterone sold by the defendants should not be sold except on the prescription of a physician, no directions for use for sale of said product over the counter to lay-persons can be adequate and that the only manner in which, under such circumstances, the requirement that "adequate directions for use" be provided on the labeling is to provide thereon that said product should be sold only by or on the prescription of a physician. Notwithstanding the fact that there exists no act of Congress or rule or regulation by any Federal administrative body or tribunal prohibiting the sale of said product except on prescription.

By reason of said arbitrary, capricious and invalid interpretation of said statute applied and enforced by said administration and the officers, agents and employees thereof defendants are not nor are any of them enabled to know whether at any time any drug product sold by them is or is not in the opinion of said Food and Drug Administration a product which may be sold over the counter to lay-persons regardless of the statements and contents of the labeling thereon or should be sold only on the prescription of a physician.

By reason of said interpretation, application and enforcement of said statute defendants herein are subjected to possible prosecution under said Federal Food, Drug and Cosmetic Act at each time a shipment of a drug product is made in interstate [124] commerce, depending entirely upon the whim, opinion, decision or belief of said Food and Drug Administration rather than upon the provisions of said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act.

By reason of said interpretation, application, and enforcement of said statute as against these defendants they are deprived of their liberty and property without due process of law in violation of Article V of the Amendments to the Constitution of the United States.

II.

Defendants further allege that should said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act, properly interpreted, empower said Food and Drug Administration to apply and enforce said Sec-

tion as hereinbefore alleged, then said Section 502 (f)(1) of the Federal Food, Drug and Cosmetic Act constitutes an invalid delegation of legislative authority to an administrative body, to wit: The Food and Drug Administration of the Federal Security Agency of the United States.

HOWLETT and ELSON,

By /s/ EUGENE M. ELSON,
Attorneys for Defendants.

Duly verified.

[Endorsed]: Filed November 10, 1949. [125]

[Title of District Court and Cause No. 10266-HW.]

AFFIDAVIT OF WALTER F. McRAE

United States of America,
Southern District of California—ss.

Walter F. McRae, being first duly sworn, deposes and says that he is Acting Chief, Los Angeles District, Food and Drug Administration, Federal Security Agency, and that the following facts and documents are derived from his personal knowledge and from the official records of the Food and Drug Administration in his possession:

(1) A seizure action under the Federal Food, Drug, and Cosmetic Act is now pending in the United States District Court for the Western District of Pennsylvania, Civil No. 2719, against both

of the Dr. Pierce remedies referred to in the Supplemental Affidavit of Martin A. Clemens. The charge in that case is false and misleading labeling.

(2) The Lydia E. Pinkham preparation referred to in the Supplemental Affidavit of Martin A. Clemens is currently under investigation by the Food and Drug Administration.

(3) Attached hereto as Exhibit A is an advertisement of the Vita [129] Pharmacal Co. that appeared on page 12, Part II, of the Los Angeles Times on January 22, 1950.

(4) Attached hereto as Exhibit B is a copy of a letter dated January 16, 1950, which Dr. Wilton L. Halverson, Director of Public Health for the State of California, sent to the California State Board of Pharmacy. This letter sets forth a resolution adopted by the Board of Health recognizing the danger of selling hormones over the counter and by mail, and urges the Board of Pharmacy to consider the matter of restricting the sale of these drugs to prescription.

(5) The California State Board of Pharmacy has announced that beginning with February 7, 1950, public hearings will be held in Los Angeles and in San Francisco with respect to the question of whether male and female hormones should be placed on a dangerous drug list and thereby restricted to sale on prescription only.

/s/ WALTER F. McRAE,
Acting Chief, Los Angeles District, Food and Drug Administration.

Subscribed and sworn to before me, this 27 day of January, 1950.

EDMUND L. SMITH,
Clerk, U. S. District Court, Southern District of California.

By /s/ WM. A. WHITE,
Deputy. [130]

Exhibit A

[Newspaper advertisement.]

12 Part II—Sunday, Jan. 22, 1950
2*Los Angeles Times

Men Over 40*

The New Hormone Tablets
Testosterone Propionate.

Full potency. Officially listed as a United States Pharmacopeia preparation and formerly available only by injection, can now be taken by mouth in this new form! Mailed in plain wrapper. Send check, cash or money order today! (Caution—take only as directed.)

50 Tablets

Postpaid $5.00, Double Strength, Postpaid $9.00

Money Back Guarantee

If, after taking these tablets for at least 10 days,

---

*Men over 40 have a higher incidence of hormone deficiency than any other group.

you don't feel that you are deriving benefit from their use, return box and the unused tablets and we will cheerfully give you your money back.

Vita Pharmacal Co., Dept. T
1109½ N. Western Ave., Hollywood 27, Calif.

Exhibit B
(Copy)

January 16, 1950.

California State Board of Pharmacy
Room 313
507 Polk Street
San Francisco, 2, California

Gentlemen:

Attention: Mr. Linnet M. Walsh, Secretary

At the meeting of the State Board of Public Health on December 9, 1949, in Los Angeles there was discussion pertaining to the sale of hormones in the State of California.

After careful review of all the circumstances of advertising, distributing and labeling methods, and the dangers of improper use of these drugs, the Board took the following action which is quoted from the minutes of its meeting of December 9.

> "Dr. Belt moved, Dr. Henderson seconded and the motion carried that recognizing the danger of selling hormones over the counter and by mail, the Board urges that the matter of restricting the sale of these drugs by prescription be considered by the State Board of Pharmacy."

The Department of Public Health, after careful study of the problems involved in the sale of these hormones considers that over-the-counter sale of the following preparations, including combinations, derivatives, compounds, and mixtures thereof is against public policy since these articles are dangerous to health except when used under medical supervision:

Testosterone
Methyl Testosterone
Testosterone Cyclopentenyl Propionate
Androsterone
Dehydro-Androsterone [132]
Estrone
Estradiol
Estriol
Equilin
Equilenin
Hippulin
Hexestrol
Benzestrol
Androstene Dione
Androstene Diol

Appropriate regulations to limit the sale of these products to prescription, with the exception of ointments containing estrogenic ingredients in a quantity providing less than 10,000 International Units of Estrone or equivalent potency per ounce, intended solely for cosmetic use, should be promulgated under Division 22, California Health and Safety Code, Dangerous Drugs Act or other appro-

priate provisions of the Health and Safety Code.

It is hereby recommended that the California State Board of Pharmacy declare the above-mentioned preparations, combinations, derivatives, compounds, and mixtures to be dangerous drugs within the meaning of Section 29001, Division 22 of the California Health and Safety Code.

The product, Stilbestrol (Diethyl-Stilbestrol) is already declared a dangerous drug under Section 29001-E of the California Health and Safety Code and no further action is needed with respect to these.

Very sincerely yours,

/s/ WILTON L. HALVERSON,
WILTON L. HALVERSON, M.D.
Director of Public Health.

[Endorsed]: Filed January 27, 1950. [133]

[Title of District Court and Cause No. 10266-HW.]

AFFIDAVIT OF ALBERT H. WELLS

State of California,
County of Los Angeles—ss.

Before me, Robert S. Roe, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Albert H. Wells, in

the county and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am 64 years of age, and am a chemist with the U. S. Food and Drug Administration, stationed at the Los Angeles District of the Administration, Los Angeles, California.

(2) On November 22, 1949, I went to the store of Vita Pharmacals, Inc., at 1109½ North Western Avenue, Los Angeles, California, accompanied by my wife.

(3) When I entered the store with my wife, one of the men from [134] the rear of the store came up behind the sales counter to wait on me. I asked him to tell me about the medicine displayed in the window as "Male Hormone Combined with Vitamin B-1."

(4) The salesman took a small carton from a shelf, broke it open, pulled out a cellophane ribbon containing units of 2 compressed tablets at regular intervals. He handed the carton and contents to me. The label appeared to be the same as Exhibit D of the Answer filed by the defendants in the case of U. S. v. El-O-Pathic Pharmacy, Inc., et al., Civil No. 10266-HW, pending in the U. S. District Court for the Southern District of California.

(5) The salesman asked me whether I had prostate trouble or cancer. I told him I did not. I told him I was taking some vitamins and thought I would inquire about this hormone preparation containing vitamins.

(6) The salesman asked my age. I told him I am 64. He handed me a bottle of 5-milligram methyl

testosterone tablets labeled in part "Ciba," saying I should take that preparation instead. After looking at the label on this bottle, I asked whether I had to see a doctor or get a prescription. He said that was not necessary. He said I could have the hormone and vitamin combination product if I wanted it, but he strongly recommended my buying the Ciba bottle. He said I would be getting more for my money. His suggestion was that the tablets be taken by placing one under the tongue three times a day. If this were done, he said, I would feel a change within a few days. I left the store saying that possibly I should consult my physician as to which product to take.

(5) On November 23, 1949, I again went to the store of Vita Pharmacals, Inc., at 1109½ North Western Avenue, Los Angeles, California.

(6) When I entered the store, another man from the rear of the store came up behind the sales counter to wait on me. I told him I had been in the day before and wanted to speak to the heavy-set gentleman who had waited on me at that time. He said that man was not in but that he would serve me instead.

(7) I explained that the other salesman had recommended the use of methyl testosterone and that I would like to purchase a bottle. The salesman [135] then showed me a large bottle of 500 tablets labeled in part "Ciba," costing $40.

(8) I asked if they had something less expensive. He showed me a small cardboard carton priced at $17. I told him I preferred to have the tablets

in a bottle. He then removed a bottle from the shelf, stating he would have to change the label before he could sell it.

(9) I asked him why he had to change the label, and he stated that he would have to put on a new label; otherwise it could not be sold. I asked him what was wrong with it. He said, "Nothing." He also stated that he had heard from those who had purchased it at their store that this preparation of 5 or 10 milligrams of Methyl-Testosterone not only benefited them for what it was designed, but also helped their rheumatism and other troubles. He emphasized to me again that this property of the drug had only been told him by other persons.

(10) I asked him which was better to be taken —the 5 milligrams or the 10 milligrams Methyl-Testosterone—and he suggested using the 10-milligram tablet. I asked him why and he stated that they were double strength and would give me quicker action. In fact, he stated that I could take more than 3 a day of the 10-milligram dosage if I preferred and without harm to myself. I asked him how I would know when they would harm me, and he said they would not harm me but that I didn't need to take them all the time but only when I needed them.

(11) He said that he would reduce the price if I would take 100 tablets of the double-strength Methyl-Testosterone. The price reduction was from $17 to $15 plus 58c tax. He volunteered the following information, by saying, "You know you cannot get these at any other place without a prescription."

(12) The salesman then departed for the rear of the store stating he would relabel the bottle. A few minutes later he returned and handed me an unsealed wrapped package. On my inquiry, he assured me that this was the 10-milligram product. I paid him $15.58 and left the store with the package.

(13) The contents of this package consisted of the following (1) a bottle with a yellow label, this label being identical with the yellow label in Exhibit A of the Answer filed by the defendants in the case of [136] U. S. v. El-O-Pathic Pharmacy, Inc., et al., Civil No. 10266-HW, pending in the U. S. District Court for the Southern District of California; (2) a circular entitled "Price List of Male Hormones," this circular being identical with Exhibit A of the affidavit of Lewis A. Schinazi in the above-identified case; and (3) a business reply envelope (no postage necessary) addressed to Vita Pharmacals, Inc., 1109½ No. Western Ave., Los Angeles 27, California.

/s/ ALBERT H. WELLS.

Subscribed and sworn to before me at Los Angeles, California, November 23, 1949.

/s/ ROBERT S. ROE,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV Effective June 30, 1940.

[Endorsed]: Filed January 27, 1950. [137]

[Title of District Court and Cause No. 10266-HW]

SUPPLEMENTAL AFFIDAVIT OF ROBERT S. ROE

United States of America,
Southern District of California—ss.

Robert S. Roe, being first duly sworn, deposes and says that he is Chief, Los Angeles District, Food and Drug Administration, Federal Security Agency, and that the following facts and documents are derived from his personal knowledge and from the official records of the Food and Drug Administration in his possession:

(1) During the months of October and November, 1949, I conducted two investigations to ascertain whether the labeling of the male hormone products distributed by Vita Pharmacal Co., et al., defendants in the above-identified proceeding, in fact cause purchasers to consult physicians before taking the drugs.

(2) Three inspectors, who work in the Los Angeles Food and Drug office under my supervision, personally interviewed a total of 19 persons who were known to have purchased the product called "Male Hormone (Methyl Testosterone) Combined with Vitamin B-1" from Vita Pharmacal Co., 1109½ North Western Avenue, [138] Los Angeles, California, during the month of September, 1949. None of these 19 purchasers was in any way connected with the Food and Drug Administration.

(3) The inspectors obtained affidavits from 5 of the 19 persons interviewed. These affidavits are

attached to my affidavit and are identified as Exhibits A, B, C, D, and E, respectively.

(4) Said inspectors, in the regular performance of their duties, have submitted written reports to me describing each of these 19 interviews. The reports are a part of the official records of the Food and Drug Administration in my custody.

(5) Of the 19 persons interviewed, 2 were in their late forties, 9 were in their fifties, 4 were in their sixties, and 4 were in their seventies.

(6) These reports show that of the 19 persons interviewed, only one person was deterred from taking any of the testosterone as a result of reading the label. After reading the label, that one person decided not to use the product until he consulted a physician to find out if it was safe and might help him. At the time of the interview, he had not yet consulted a physician.

(7) Another of the 19 persons interviewed had ordered the drug, but about the time that he received it he had read a magazine or newspaper article warning of the dangers involved in the unsupervised use of hormones. For this reason, he decided not to take any.

(8) Still another of the 19 persons interviewed had been buying male hormones from El-O-Pathic Pharmacy (later Vita Pharmacals) since June or July of 1949. Prior thereto he had been taking what he thought were male hormone tablets prescribed for him by a physician some time ago. This person felt that the hormone tablets he obtained from El-O-Pathic Pharmacy were not of as much

value as those he had obtained on prescription. He also thought they caused tension around his heart and nervousness. For these reasons, he decided to discontinue taking these tablets.

(9) The remaining 16 persons of the 19 interviewed commenced taking the male hormones on receiving them from Vita Pharmacals without first consulting a physician.[1] Of these 16, 1 stated he had consulted a physician [139] about 3 months before ordering the hormones and had been advised that the physician would not recommend male hormones for a man of his age. Nevertheless, that person ordered the hormones by mail and took them without further consultation with his physician.

Five of the 16 who took the hormones without consulting a physician said that they thought they were safe in doing so because at some time in the past a physician had given them "hormone" shots or had prescribed hormones for them. Of these 5, one had received hormones from his physician a year before; three persons had received hormones from their physicians 2 years before; and one person had received hormones from his physician 4 years before.

Another of these 16 persons had been purchasing male hormones from El-O-Pathic Pharmacy and Vita Pharmacals, Inc., for 2 years. He had not consulted a physician before he began taking the hor-

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[1]One of these 16 persons was not at home when the inspector called, but the wife of that person furnished the inspector with the information sought.

mones and he continued taking them without consulting a physician. In September of 1949, in the course of being given a physical examination by a physician, he mentioned that he was taking hormones and he states he was advised he could continue taking them.

Another of these 16 persons began taking the hormones but shortly thereafter was advised by a friend that hormones may cause cancer and should not be used without medical advice. Whereupon, that person discontinued taking the hormones.

/s/ ROBERT S. ROE,
Chief, Los Angeles District, Food and Drug Administration.

Subscribed and sworn to before me, this 1st day of December, 1949.

EDMUND L. SMITH,
Clerk, U. S. District Court, Southern District of California.

By /s/ WM. A. WHITE,
Deputy. [140]

Exhibit A

AFFIDAVIT

FD463a

State of California
County of Los Angeles

Before me, Ola H. Bain, an employee of the Federal Security Agency, Food and Drug Admin-

istration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Walter E. Wright in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am 71 years of age.

I reside at 200 S. Putney Ave., San Gabriel, Calif.

About 3 months ago I inquired of Dr. Edison our family physician who maintains an office on Rosemead Avenue near my home, regarding the advisability of taking male sex hormones. The doctor said that he would not recommend them for a man of my age.

Soon thereafter I noticed a hormone advertisement by the El-O-Pathic Pharmacy in the Los Angeles Times and I decided to try the product. I ordered and received the 5 mg. Testosterone by mail, and subsequently re-ordered once or twice.

About 2 months ago I received a notice from the El-O-Pathic Pharmacy advising that the Vita-Pharmacals Company was taking over distribution of their products. [141]

Soon thereafter I ordered and received from this firm (Vita-Pharmacals Co.) a 30 tablet package of the combined hormone and vitamin product.

Taking the hormone preparations has resulted in

considerable improvement in my physical, mental and sex powers.

I have never been advised by a physician that my own hormone output was deficient or that I should take the products for any reason whatsoever, and I have not consulted a physician since receiving the El-O-Pathic or Vita-Pharmacals hormone preparations.

/s/ WALTER E. WRIGHT.

Subscribed and sworn to before me at San Gabriel, Calif., this 22nd day of November, 1949.

/s/ OLA H. BAIN,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, [142] 1940.

Exhibit B

Affidavit

State of California
County of Los Angeles

Before me, Robert W. Jennings, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Mr. K. V. Johnson in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am a man of 72 years of age now residing at 10356 San Carlos, South Gate, California. The following information is given of my own free will and is true to the best of my knowledge.

Immediately prior to Sept. 19, 1949, I ordered tablets consisting of Male Hormone and Vitamin B-1 from the Vita Pharmacals Inc. of 1109½ N. Western Ave., Hollywood, California. This order was the result of noting hormone advertisements in the local newspaper.

On or about September 19, 1949, I received a shipment in the mail from the above-named company and this consisted of literature about hormones and vitamin B-1 along with a package of the tablets. This package was marked with the name of "Maywood Pharmacal Company" but in addition carried a sticker-label designating re-orders were to be sent to the "Vita Pharmacals," "distributors." There were 60 tablets in a cellophane roll within the package (or box), 30 of these being brown in appearance and 30 yellow in color. One tablet of each color was included in each section of the cellophane roll of merchandise. [143]

My purpose in purchasing the Hormone-Vitamin B-1 tablets was an attempt in aiding, is possible, a feeling of being tired and lack of energy. My thought was that these tablets might be of such value to me.

I took 50 of the 60 tablets sent to me, these being taken according to the direction on the box—that is, one tablet of each color per day—and feel that the product did me no harm and yet was of no value. I do have a catarrh condition and when taking these

tablets seemed to have a nose and throat drainage. I do not know if the drainage was caused by the tablets, but when I ceased taking the product, the condition ceased to exist.

I have never consulted a physician relative to the taking of male hormones.

/s/ K. V. JOHNSON.

Subscribed and sworn to before me at 10356 San Carlos, South Gate, California, this 27th day of October, 1949.

/s/ ROBERT W. JENNINGS,
Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, [144] 1940.

Exhibit C
Affidavit

FD463a
F.S.A. F.D.A.
State of California
County of Los Angeles

Before me, Robert W. Jennings, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Mr. E. C. Fessler in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am a man of 52 years of age now residing at 4831 East 61st St., Maywood, California. The following information is given of my own free will and true to the best of my knowledge.

I have not seen a physician in over 10 years and until recently have never taken Hormone preparations. Approximately one month ago, after noting Hormone-Vitamine B-1 tablet ads in the Los Angeles Examiner paper, I ordered a supply of 60 tablets from the Vita Pharmacal Inc., N. Western Ave., Hollywood. These were received and found to be tablets in a cellophane stripping. Half of the tablets were brown in color and half were yellow. I took these as directed on the box and later ordered a second shipment of tablets. These were received approximately 1 week ago and consisted of white tablets of Male Hormone only, in the amount of 100/5 mg tablets. I have thrown away the containers for both shipments of tablets but remember their directions on the label.

I purchased this merchandise in an attempt to alleviate a tired, all-in feeling which I have had at times for the last eight or nine years. I have only about 3 days dosage remaining from my first shipment of merchandise and on completion of this will take the tablets sent me on the second order. To date I have had no results and can see no harm from those tablets taken. I intend to take all tablets in order to give the merchandise a fair trial. If I have

not improved by that time, I intend to cease use of them.

/s/ E. C. FESSLER.

Subscribed and sworn to before me at 4831 E. 61st St., Maywood, California, this 27th day of October, 1949.

/s/ ROBERT W. JENNINGS,
Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, [145] 1940.

Exhibit D

Affidavit

FD463a

State of California,
County of Los Angeles.

Before me, Robert C. Brandenburg, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared C. W. Mingura in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am a man of 47 years of age. On or about 9/12/49, in response to an ad I read in the Los Angeles Daily News, I ordered some Male Hormones from the Vita Pharmacal Company, Los Angeles.

The hormones were sent to me in a day or so via U.S. Mail. I read the label on the product but didn't follow the directions—I took the material at only about half the suggested frequency. I ordered the product because I thought that the combination of Vitamin B-1 and Hormones might be good for me and give me more energy. I feel that I obtained neither good nor bad results from the use of the product, but then again I didn't expect too much in the first place. I was not told by a doctor to take these hormones, and no doctor has ever told me that I need hormones.

/s/ C. W. MINGURA,
409 E. 21st St., Los Angeles, Calif.

Subscribed and sworn to before me at Los Angeles, California, this 22nd day of November, 1949.

/s/ ROBERT C. BRANDENBURG,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, [146] 1940.

Exhibit E
Affidavit

FD463a

State of California
County of Los Angeles

Before me, Robert C. Brandenburg, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of Janu-

ary 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared W. L. Durrive in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am a man of 68 years of age. On or about 9/8/49, in response to an ad I read in the Los Angeles Examiner, I ordered some Male Hormones from the Vita Pharmacal Company, Los Angeles. The hormones were sent to me in a day or so via U.S. Mail. I didn't bother reading the label of the product other than the suggested dosage. I feel that the hormones built me up and made me feel better. I was not told by a doctor to take these hormones, and no doctor has ever told me that I need hormones.

/s/ W. L. DURRIVE,
2415 West Jefferson Ave.,
Los Angeles, Calif.

Subscribed and sworn to before me at Los Angeles, California, this 22nd day of November, 1949.

/s/ ROBERT C. BRANDENBURG,
Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, 1940.

[Endorsed]: Filed January 27, 1950. [147]

In the United States District Court for the Southern District of California, Central Division

Civil No. 10266-HW

UNITED STATES OF AMERICA,

Plaintiff,

vs.

EL-O-PATHIC PHARMACY, a Corporation; MARTIN A. CLEMENS, an Individual, and VITA PHARMACALS, INC., a Corporation,

Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW ON PRAYER FOR PRELIMINARY INJUNCTION

This Court, having considered the pleadings, affidavits, briefs, and oral arguments relating to the plaintiff's prayer for a Preliminary Injunction in this cause, and having denied said prayer on January 11, 1950, now makes the following Findings of Fact and Conclusions of Law, but expressly refrains from making any determination with respect to the ultimate issues of fact and law:

Findings of Fact

(1) If the defendants are violating the Federal Food, Drug, and Cosmetic Act, the public interest can be substantially protected by an early trial on the plaintiff's prayer for a Permanent Injunction.

(2) This cause was set for trial in this Court on January 24, 1950, on the plaintiff's prayer for a Permanent Injunction, and on stipulation of the parties the trial date was continued until January 31, 1950. [148]

Conclusions of Law

(1) Where the United States seeks a Preliminary Injunction to prevent alleged violations of the Federal Food, Drug, and Cosmetic Act, and it appears that an early trial can be had on the prayer for a Permanent Injunction which will substantially protect the public interest involved, a Preliminary Injunction should not issue.

(2) The plaintiff's prayer for a Preliminary Injunction is denied.

Dated: Jan. 30th, 1950.

/s/ HARRY C. WESTOVER,
United States District Judge.

Received copy of the within Findings of Fact and Conclusions of Law this 27th day of January, 1950.

/s/ EUGENE M. ELSON,
Attorney for Defendants.

Judgment entered Jan. 30, 1950.

[Endorsed]: Filed January 30, 1950. [149]

[Title of District Court and Cause No. 10266-HW.]

STIPULATION AS TO RECORD

In order that this case may be disposed of as quickly as possible,

It Is Stipulated by the parties hereto, through their respective counsel, that the complete record of this case shall consist of the following documents, all of which are filed in Civil No. 10266-HW, unless otherwise stated:

(1) The Complaint for Injunction and the Amendment to Complaint for Injunction filed by the plaintiff;

(2) The supporting affidavits filed by the plaintiff together with their exhibits—namely, the affidavits of Mr. Robert S. Roe, Dr. Clinton Hobart Thienes, Dr. Elmer Belt, Dr. Ian Macdonald, and Mr. Lewis A. Schinazi;

(3) Judge Jacob Weinberger's Order Granting Temporary Restraining Order, dated September 2, 1949;

(4) Judge Jacob Weinberger's Order to Show Cause, dated September 2, 1949;

(5) Stipulation, Consent, and Order, signed by Judge Peirson M. Hall, [150] dated September 6, 1949, continuing hearing on Order to Show Cause;

(6) Stipulation, Consent, and Order, signed by

Judge Peirson M. Hall, dated September 26, 1949, continuing hearing on Order to Show Cause;

(7) Answer and Amendment to the Answer filed by the defendants;

(8) Stipulation Permitting Filing of Amendment to Answer, dated November 10, 1949;

(9) Affidavit of Martin A. Clemens and two supplemental Affidavits of Martin A. Clemens;

(10) Affidavit of Eugene M. Elson;

(11) Findings of Fact and Conclusions of Law of Judge Westover denying plaintiff's prayer for a Preliminary Injunction;

(12) Supplemental Affidavit of Robert S. Roe, subject to any objections as to relevancy and materiality;

(13) Affidavit of Albert H. Wells, subject to any objections as to relevancy and materiality;

(14) Affidavit of Walter F. McRae, subject to any objections as to relevancy and materiality;

(15) The Information filed by the Government in United States v. El-O-Pathic Pharmacy and Martin A. Clemens, No. 20596-Criminal (S.D. Calif.);

(16) The complete transcript of proceedings in the case described in paragraph (15), including exhibits, shall be considered part of the record of this case subject to any objections as to its relevancy and materiality;

(17) Stipulation and Order filed January 17, 1950, continuing the trial in this cause for one week.

ERNEST A. TOLIN,
United States Attorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief of Civil Division.

/s/ TOBIAS G. KLINGER,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

HOWLETT and ELSON,
By /s/ EUGENE M. ELSON,
Attorney for Defendants.

[Endorsed]: Filed January 31, 1950. [151]

At a stated term, to wit: The September Term, A.D. 1949, of the District Court of the United States of America, within and for the Central Division of the Southern District of California, held at the Court Room thereof, in the City of Los Angeles on Tuesday, the 31st day of January in the year of our Lord one thousand nine hundred and fifty.

Present: The Honorable Charles C. Cavanah,
District Judge.

[Title of Cause No. 10266-HW-Civil]
and
[Title of Cause No. 10391-HW-Civil]

ORDER CAUSES CONSOLIDATED

These consolidated causes coming on for trial: Geo. E. Danielson, Ass't. U. S. Att'y., appearing as

counsel for Gov't.; E. M. Elson, Esq., appearing as counsel for defendants; Attorney Danielson answers ready; and Attorney Elson answers ready and states that the causes are not consolidated for trial.

The Court orders the causes consolidated for trial and states it will bear in mind the separate contentions in each cause.

Attorney Danielson make opening statement and reads stipulation as to the record in each case, and said stipulation is filed herein.

Counsel having rested upon the record stipulated to in each case, Attorney Danielson argues in behalf of plaintiff. At 10:55 a.m. Court recesses.

At 11:10 a.m. court reconvenes herein and all being present as before, including counsel for both sides; Attorney Danielson argues further. Attorney Elson argues for defendants. At 11:55 a.m. court recesses. [259]

At 2 p.m. court reconvenes herein and all being present as before, including counsel for both sides; Attorney Elson argues further for plaintiff in closing. Attorney Elson argues further. Counsel stipulate to furnish transcript and the Court orders cause stand submitted.

Supplemental authorities of plaintiff are filed. [260]

At a stated term, to wit: The September Term, A. D. 1949, of the District Court of the United States of America, within and for the Central Division of the Southern District of California, held at the Court Room thereof, in the City of Los Angeles, on Friday the 3rd day of February in the year of our Lord one thousand nine hundred and fifty.

Present: The Honorable Charles E. Cavanah,
District Judge.

[Title of Cause No. 10266-HW-Civil]

and

[Title of Cause No. 10391-HW-Civil]

ORDER CAUSES REFERRED FOR RE-ASSIGNMENT

Geo. E. Danielson, Ass't. U. S. Att'y., appearing as counsel for Gov't., and Hallam Mathews, Esq., appearing in behalf of Eugene M. Elson, Esq., attorney for defendants, now come before the Court in Chambers, whereupon the Court states that after the causes were finally submitted, the Court finds itself disqualified from proceeding further in these consolidated causes and orders same referred to Judge McCormick for re-assignment. [261]

[Title of District Court and Cause No. 10,266-HW.]

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff having filed a Complaint praying for a temporary restraining order, for a preliminary injunction, and for a permanent injunction; and the Court having granted the prayer for a temporary restraining order; and the defendants having appeared and answered; and the Court having denied the prayer for a preliminary injunction; and the cause having come on for trial on the plaintiff's prayer for a permanent injunction; and this cause having been consolidated for trial with U. S. vs. Hudson Products Co., et al., No. 10-391-HW Civil; and the parties having offered documentary evidence by stipulation; the Court now makes the following Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure:

Findings of Fact

(1) Defendant El-O-Pathic Pharmacy, a corporation, was dissolved on September 7, 1949, and is no longer in existence.

(2) Defendant Vita Pharmacals, Inc., is a corporation organized under [152] the laws of California. It has its principal place of business at 1109½ No. Western Avenue, Hollywood, California. It has purchased all of the assets and liabilities of said El-O-Pathic Pharmacy.

(3) Defendant Martin A. Clemens is the general manager of defendant Vita Pharmacals, Inc., and is primarily responsible for the policies and activities of said corporation.

(4) For some years, defendant Martin A. Clemens has been engaged in the interstate and intrastate distribution of male and female hormone drugs, conducting such business at first in his own name and then as general manager of corporations such as El-O-Pathic Pharmacy and Vita Pharmacals, Inc.

(5) Defendant Clemens and defendant El-O-Pathic Pharmacy were convicted in this Court on July 13, 1949, in Docket No. 20596-Criminal, of violating the Federal Food, Drug, and Cosmetic Act by reason of their distribution of misbranded male and female hormone drugs.

(6) There is no evidence that defendants have continued the distribution of female hormone drugs since July 13, 1949.

(7) Subsequent to July 13, 1949, defendants Clemens and Vita Pharmacals, Inc., have changed the labeling of the male hormone drugs which they distribute. They will probably continue the interstate and intrastate distribution of said drugs as presently labeled on a large scale unless restrained from so doing by this Court.

(8) Four of the male hormone drugs which defendants sell over-the-counter and on mail order consist of:

(a) Methyl testosterone tablets (10 milligrams)

(b) Methyl testosterone tablets (25 milligrams)

(c) Methyl testosterone linguets (5 milligrams)

(d) Methyl testosterone linguets (10 milligrams)

These drugs are sold in quantities ranging from 50 tablets per package to 1000 tablets per package.

(9) Said drugs are manufactured by Ciba Pharmaceutical Products, Inc., Summit, New Jersey; by Roche-Organon, Inc., Nutley, New Jersey; and by Schering Corporation, Bloomfield, New Jersey. Said drugs are shipped interstate by the [153] manufacturers to defendant Vita Pharmacals, Inc.

(10) During the interstate movement of said drugs from said manufacturers to said defendant Vita Pharmacals, Inc., the labeling of each of said drugs bears the legend: "Caution: To be dispensed only by or on prescription of a physician."

(11) Defendants Clemens and Vita Pharmacals, Inc., however, do not require a physician's prescription in their resale of said drugs.

(12) Defendants Clemens and Vita Pharmacals, Inc., repackage and relabel said drugs after receiving them from the manufacturers. The labels which said defendants use are those which comprise Exhibit B of the Affidavit of Martin A. Clemens.

(13) Defendants Clemens and Vita Pharmacals, Inc., also ship interstate on mail order a male hormone drug consisting of methyl testosterone combined with Vitamin B-1 in linguet form. Said drug is labeled as set forth in Paragraph 13(a) of the Amendment to Complaint for Injunction.

(14) The labeling of each of the male hormone drugs which said defendants distribute uses the word "physician" four times in such phrases as "under supervision of a physician." Said labeling includes a statement that a physician should be consulted before taking testosterone.

(15) The labeling of each of said drugs contains adequate directions for use.

(16) The labeling of each of said drugs contains adequate warnings.

(17) There is medical opinion on both sides as to whether there are ill effects from taking said drugs.

(18) Said drugs are not dangerous to health when taken as directed in the labeling.

(19) The plaintiff has not sustained its burden of proof with respect to its allegations in issue.

(20) The plaintiff has not established that a 5 milligram linguet of methyl testosterone taken once daily is ineffective in the treatment of male hormone deficiency. [154]

Conclusions of Law

(1) This Court has jurisdiction over the subject matter of this cause and the parties thereto.

(2) The Complaint, as amended, is dismissed as to defendant El-O-Pathic Pharmacy, a corporation, since said defendant has been dissolved and is no longer in existence.

(3) The male hormone drugs distributed by defendants Martin A. Clemens and Vita Pharmacals, Inc., are not misbranded within the meaning of 21 U.S.C. 352(f)(1) since the suggestion in the labeling of said drugs that they be taken in consultation with a physician constitutes adequate directions for use.

(4) The male hormone drugs distributed by said defendants are not misbranded within the meaning of 21 U.S.C. 352(f)(2) since the suggestion in the labeling of said drugs that they be taken in consultation with a physician constitutes adequate warning against use in those pathological conditions where their use may be dangerous to health.

(5) The male hormone drugs distributed by said defendants are not misbranded within the meaning of 21 U.S.C. 352(j) since said drugs are not dangerous to health when used in the dosage and with the frequency and duration recommended in the labeling if the drugs are taken as suggested in the labeling, namely, in consultation with a physician.

(6) The male hormone drugs [the 5 milligram methyl testosterone linguets, and the combination methyl testosterone and Vitamin B-1 linguets] dis-

tributed by said defendants are not misbranded within the meaning of 21 U.S.C. 352(a) since it has not been established that the daily intake of 5 milligrams of methyl testosterone in linguet form is ineffective in the treatment of male hormone deficiency.

(7) The plaintiff's prayer for a permanent injunction is denied.

Dated: May 22nd, 1950.

/s/ HARRY C. WESTOVER,
United States District Judge.

Affidavit of Service by Mail Attached.

[Endorsed]: Filed May 22, 1950. [155]

In the United States District Court, in and for the Southern District of California, Central Division

No. 10,266-HW Civil

UNITED STATES OF AMERICA,
Plaintiff,

vs.

EL-O-PATHIC PHARMACY, a Corporation, MARTIN A. CLEMENS, an Individual, and VITA PHARMACALS, INC, a Corporation,
Defendants.

JUDGMENT

Plaintiff having filed a Complaint praying for a

temporary restraining order, for a preliminary injunction, and for a permanent injunction; and the Court having granted the prayer for a temporary restraining order; and the defendants having appeared and answered; and the Court having denied the prayer for a preliminary injunction; and the cause having come on for trial on the plaintiff's prayer for a permanent injunction; and this cause having been consolidated for trial with United States v. Hudson Products Co., et al., No. 10,391-HW Civil; and the parties having offered documentary evidence by stipulation; and the Court having filed Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure;

It Is Therefore Ordered, Adjudged, and Decreed that the plaintiff's prayer for a permanent injunction be, and is hereby denied, and that the Complaint for Injunction be, and is hereby, dismissed.

Dated: May 22, 1950.

/s/ HARRY C. WESTOVER,
U. S. District Court Judge.

Judgment entered May 22, 1950.

[Endorsed]: Filed May 22, 1950. [157]

In the United States District Court, for the Southern District of California, Central Division

Civil Action No. 10391-PH

UNITED STATES OF AMERICA,
Plaintiff,

vs.

HUDSON PRODUCTS COMPANY, a Corporation, and Its Subsidiary Firm Doing Business Under the Fictitious Name and Style, MAYWOOD PHARMACAL COMPANY, and ALLEN H. PARKINSON, an Individual,
Defendants.

COMPLAINT FOR INJUNCTION

[21 U.S.C. 332(a), 331(a), 352(a), 352(f)(1) and (2)]

United States of America, plaintiff herein, by and through James M. Carter, United States Attorney for the Southern District of California, Central Division, respectfully represents to this Honorable Court as follows:

1. This proceeding is brought under section 302(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 332(a)], hereinafter referred to as the "Act," specifically vesting jurisdiction in the several United States District Courts to restrain violations of section 301 of said Act [21 U.S.C. 331] as hereinafter appears more fully.

2. The defendant, Hudson Products Company, is a corporation having its principal place of business at 1067 E. Anaheim Street, Long Beach, California. The Hudson Products Company also trades under the fictitious name and style of Maywood Pharmacal Company, 6912 Hollywood Boulevard, Hollywood, California; all [158] mail orders received by the Maywood Pharmacal Company are filled and mailed by Hudson Products Company. The defendant, Allen H. Parkinson, who resides in the County of Los Angeles, State of Cailfornia, within the jurisdiction of this Honorable Court, is the president of said Hudson Products Company and is primarily responsible for the policies and activities of the firm.

3. Said Hudson Products Company, Maywood Pharmacal Company, and Allen H. Parkinson, are distributors of certain male and female hormone drugs; the male hormone drugs consist of methyl testosterone tablets (10 milligrams), methyl testosterone linguets (5 milligrams), methyl testosterone linguets combined with a small amount of vitamin B-1 (daily dosage of testosterone when taken as directed being 5 milligrams); the female hormone drugs consist of tablets containing 0.1 milligram alpha-estradiol.

4. In newspaper and magazine advertising, defendants represent and suggest that male hormones are efficacious for the treatment of alleged symptoms of middle age such as nervousness, tiredness, and uncertainty about the future; that the adminis-

tration of male hormones causes the years after 40 to be the best time of a man's life; and that the administration of male hormones is effective in overcoming sexual impotence and in causing sexual rejuvenation.

5. Said defendants are also circularizing former customers, offering a revised formula containing methyl testosterone with vitamin B-1 in linguet form. Said defendants are also circularizing druggists in the State of California and other states offering Hudson Hormones on a wholesale basis. The circular describes the products offered as methyl testosterone tablets, both with and without vitamin B-1; it states that the Hudson Products Company, Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drug store; it further states that these drugs are to be sold "over-the-counter"—e.g., without a physician's prescription.

6. The methyl testosterone linguets are offered for sale and shipped in interstate commerce under the following labeling: [159]

Copy of Carton Label

[Front and Rear Panel Identical]

30 5 mg. each

Hudson Hormone Tablets for Men

Each tablet contains 5 mg. Methyl Testosterone. (For absorption under the tongue or inside the

cheek.) For use when Methyl Testosterone is indicated for relief of symptoms of Male Hormone deficiency.

Hudson Products Co.
Long Beach 5, Calif.

5 Mg. Regular Strength

[Side Panels—identical]

Hudson Hormone Tablets

This is a new and more effective male hormone tablet. It is not swallowed, but is held in the mouth between the teeth and the cheek until the hormone is completely absorbed by the cheek tissues and goes directly into the blood stream. This method by-passes the liver, where any hormone that is taken orally is partially deactivated. This tablet is specially made to dissolve slowly (about 30 minutes).

Notice: This new tablet is 2 to 3 times more effective than hormone tablets that are taken orally.

Copy of Bottle Label

[Side Panel]

Notice: It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, [160] since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.

Suggested Dosage: One tablet daily shortly before retiring. Tablets should be held between gum and

cheek, or under tongue, and allowed to dissolve slowly so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician.

[Front Panel]

30 Tablets 5 mg. each

Hudson Hormones for Men 5 mg.

Regular Strength Methyl Testosterone

Hudson Products Co.
Long Beach 5, California
Distributors

[Side Panel]

Directions: For use by adult males mildly deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.
Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, [161] or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except

under constant direct supervision of a physician.

7. The defendants also offer for sale and ship in interstate commerce linguets containing methyl testosterone and vitamin B-1 under the following labeling:

Copy of Carton Label

[Front Panel]

30 Tablets

Male Hormone (Methyl Testosterone)
Combined With Vitamin B-1

Open
Here

Directions: For use when Methyl Testosterone is indicated for palliative relief of symptoms of male hormone deficiency by those males mildly deficient in male hormone and where small dosages of hormone are indicated. Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B-1 (Thiamin Hydrochloride) in a specially prepared base for sublingual use. See instructions on back. [162]

Maywood Pharmacal Company

[Back Panel]

Double-Your-Money-Back Agreement

If you use Maywood Hormones as directed and are not fully satisfied with the results you have ob-

tained, return the box and the unused tablets to Maywood Pharmacal Company and we will cheerfully refund double your money.

Suggested Dosage: One light tablet upon arising before breakfast, and one dark tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosages can be extended from 3 to 6 months, under supervision of a physician.

Caution: The male hormone should not be taken by anyone with carminoma of the prostate, or urinary retention possibly due to carcinoma of the prostate, or by anyone with cardio-vascular disease, or debilitation due to disease. Take only as directed. Adolescents must not use except under constant direct supervision of a physician.

[Top Panel]

The hormones in this package are of purest laboratory-controlled potency. Maywood Hormones may be obtained in 30, 60 and 180-tablet packages.

Distributed by
Maywood Pharmacal Company
6912 Hollywood Blvd., Hollywood 28, Calif.

[Bottom Panel]

Methyl Testosterone combined with Vitamin B-1
Maywood Pharmacal Company

Copy of Label Wrapped Around

Pasteboard Carton

[Front Panel]

30 Tablets

Male Hormone (Methyl Testosterone)
Combined With Vitamin B-1

Open
Here

Directions: For use by adult males mildly deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.
Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B-1 (Thiamin Hydrochloride) in a specially prepared base for sublingual use. See instructions on back.

Maywood Pharmacal Company

[Side Panel]

Pull out cellophane tape and tear off individual "Packet-Pak" at perforation. Each packet contains average daily dose of one light (morning) and one dark (evening) tablet. Tear off corner of

packet to extract morning tablet, then cellophane can be folded to protect evening tablet until taken.

[Rear Panel]

Suggested Dosage:

One light tablet upon arising before breakfast, and one dark tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician.

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.

[Side Panel]

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve

symptoms not associated with male hormone deficiency. [165]

8. Defendants violate section 301(a) of the Act [21 U.S.C. 331(a)] by causing the introduction into interstate commerce of methyl testosterone linguets, labeled as described in paragraphs 6 and 7, which are misbranded in the following respects:

(a) Within the meaning of section 502(a) of the Act [21 U.S.C. 352(a)] in that the labeling is false and misleading, since it represents and suggests that the suggested daily dosage is efficacious for use in the treatment of male hormone deficiency, whereas the suggested daily dosage would be entirely ineffective for that purpose;

(b) Within the meaning of section 502(f)(1) of the Act [21 U.S.C. 352 (f)(1)] in that the labeling of said linguets fails to bear adequate directions for use in all conditions for which said linguets are prescribed, recommended, and suggested in their labeling and their advertising matter disseminated and sponsored by the defendants;

(c) Within the meaning of section 502(f)(2) of the Act [21 U.S.C. 352 (f)(2)] in that the labeling of said linguets fails to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling

is couched is inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of cancer of the prostate gland or may cause sterility.

9. With respect to the methyl testosterone tablets, it is likely that the defendants will cause the same violation of section 301(a) of the Act [21 U.S.C. 331(a)] as they are causing with respect to the methyl testosterone linguets, (as described in paragraph 8(a), (b), and (c) above), since the defendants have in the past sold these products freely in interstate commerce, without a physician's prescription, and without adequate warnings. [166]

10. With respect to the alpha-estradiol preparations, it is likely that the defendants will cause the same or similar violations of section 301(a) of the Act [21 U.S.C. 331(a)] as they are causing with respect to the methyl testosterone linguets (as described in paragraphs 8(a), (b), and (c) above), since the unrestricted use of alpha-estradiol preparations by women may accelerate the malignant growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system; and since the defendants have in the past sold these products freely, without a physician's prescription, and without adequate warnings.

11. In the case of the United States v. Allen H. Parkinson, an individual trading as Hudson Products Company, No. 20642-Criminal, this Court on July 13, 1949, convicted Allen H. Parkinson, an individual, trading as Hudson Products Company,

for the distribution of misbranded male and female hormones in violation of the Act. The hormones there involved included methyl testosterone tablets and alpha-estradiol tablets. In announcing judgment, the Court stated it was convinced beyond a reasonable doubt that these hormone preparations constituted not merely a potential danger but also an actual danger to health when used indiscriminately by the lay person. The Court also stated that the therapeutic claims which the defendant made for these products far exceeded the benefits that could be derived from them.

12. In less than a month after the aforesaid conviction, the defendants embarked upon a widespread promotion of the methyl testosterone-containing products in essentially the same misbranded condition as were the products involved in the criminal prosecution. The revised labelings and the marketing of methyl testosterone linguets in combination with vitamin B-1 for practical purposes constitute a continuation of the business declared illegal by this Court in the aforesaid criminal prosecution.

13. The plaintiff is informed and believes that unless restrained by the Court the defendants will continue to introduce and deliver for introduction into interstate commerce the said articles of drug misbranded in the manner aforesaid.

Wherefore, plaintiff prays: [167]

That the defendants, Hudson Products Company, a corporation, its subsidiary firm doing business under the fictitious name and style, Maywood Phar-

macal Company, and Allen H. Parkinson, and each and all of their officers, agents, servants, employees, and attorneys, and all persons in active concert or participation with any of them, be perpetually enjoined from directly or indirectly causing to be introduced or delivered for introduction into interstate commerce, in violation of section 301(a) of the Act [U.S.C. 331(a)] the articles of drug, hereingbefore described, misbranded within the meaning of sections 502(a), 502(f)(1), or 502(f)(2) of the Act [21 U.S.C. 352(a), 352(f)(1), or 352(f)(2)].

That an Order be made and entered directing the defendants to show cause at a time and place to be designated in such order why they should not be enjoined and restrained as herein prayed during the pendency of this action; that upon the hearing of said order to show cause, a Preliminary Injunction be granted restraining the defendants as herein prayed during the pendency of this action;

That the plaintiff be given judgment for its costs herein and for such other and further relief as to the Court may seem just and proper.

JAMES M. CARTER,
United States Attorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney
Chief, Civil Division.

/s/ GEORGE E. DANIELSON,
Assistant U. S. Attorney.

[Endorsed]: Filed September 29, 1949. [168]

[Title of District Court and Cause No. 10391-PH.]

ORDER TO SHOW CAUSE

Upon the Complaint of the Plaintiff, United States of America, filed in the above-entitled case on September 29, 1949, and good cause appearing therefor,

It Is Hereby Ordered that the defendants, Hudson Products Company, Maywood Pharmacal Company, and Allen H. Parkinson, be and appear before this Court in the Courtroom of Judge Peirson M. Hall, United States Post Office and Courthouse Building, 312 North Spring Street, Los Angeles, California, at the hour of 2:00 p.m., on the 24th day of October, 1949, then and there to show cause, if any there be, why a preliminary injunction should not be issued enjoining and restraining said defendants, during the pendency of this action, from further violations of the Federal Food, Drug, and Cosmetic Act, as prayed in said Complaint.

And It Is Further Ordered that the service of a copy of this Order by the United States Marshal, or one of his deputies, together with a copy of the said Complaint, be made upon each of the said defendants on or before the 10th day of October, 1949, and that the same shall be deemed sufficient service of said Order and Complaint.

Dated: September 29, 1949.

/s/ PAUL J. McCORMICK,
United States District Judge.

[Endorsed]: Filed September 29, 1949. [170]

[Title of District Court and Cause No. 10391-PH Civil.]

STIPULATION REGARDING MEDICAL AFFIDAVITS

It is stipulated by and between the plaintiff, United States of America, and the defendants, Hudson Products Company, Maywood Pharmacal Company, and Allen H. Parkinson, through their respective counsel, that the affidavits of Dr. Thienes, Dr. Belt, and Dr. Macdonald, heretofore filed by the plaintiff in this Court in the case of United States v. El-O-Pathic Pharmacy, et al., No. 10266-PH, shall be deemed also to have been filed in the instant proceeding.

A certified copy of each of said affidavits is attached hereto.

JAMES M. CARTER,
United States Attorney,

CLYDE C. DOWNING,
Assistant U. S. Attorney
Chief, Civil Division,

/s/ GEORGE E. DANIELSON,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

/s/ EUGENE M. ELSON,
Attorney for Defendants.

[Endorsed]: Filed October 20, 1949. [174]

[Title of District Court and Cause No. 10391-PH Civil.]

AFFIDAVIT OF ROBERT S. ROE

United States of America,
Southern District of California—ss.

Robert S. Roe, being first duly sworn, deposes and says that he is Chief, Los Angeles District, Food and Drug Administration, Federal Security Agency, and that the following facts are derived from his personal knowledge and from the official records of the Food and Drug Administration in his possession:

(1) On July 13, 1949, Allen H. Parkinson, an individual, trading as Hudson Products Company, Long Beach, California, was convicted in this Court of violating the Federal Food, Drug, and Cosmetic Act. (No. 20652-Criminal.) The substance of the charges upon which the defendant was convicted was the indiscriminate sale of dangerous drugs for lay use, together with the making of extravagant therapeutic claims for those drugs. The drugs involved in that case were male and female sex hormone preparations including methyl testosterone tablets and alpha-estradiol preparations.

(2) Defendant Allen H. Parkinson is now continuing a large scale business in male and female sex hormones. Mr. Parkinson is the President of the Hudson Products Company, a corporation do-

ing business in Long Beach, California, and is responsible for the policies and activities of that company as well as of the Maywood Pharmacal Company, which is a fictitious name under [171] which the Hudson Products Company does some of its business. The practice of these defendants has been to promote a widespread interstate distribution of the above-described drugs by creating the impression through labeling and newspaper advertising that such drugs have miraculous powers of sexual rejuvenation for men over 40, and that they will alleviate disease conditions in women caused by change of life. In selling these products direct to laymen by mail-order purchases, said defendants do not require a physician's prescription.

(3) The current methods of distribution adopted by the defendants with respect to methyl testosterone linguets subsequent to the conviction of Allen H. Parkinson are as described in paragraphs 4, 5, 6, and 7 of the Complaint filed in the instant case.

(4) Defendants are in the midst of unloading a large quantity of these drugs without prescription, upon the public. Defendants are thereby now caus-

ing immediate and irreparable injury, loss, and danger to the public for the reasons stated in the affidavits of Dr. Thienes, Dr. Belt, and Dr. Macdonald.

/s/ ROBERT S. ROE,

Chief, Los Angeles District, Food and Drug Administration.

Subscribed and sworn to before me, this 20th day of October, 1949.

EDMUND L. SMITH,

Clerk, U. S. District Court, Southern District of California.

By /s/ WM. A. WHITE,

Deputy.

Affidavit of Service by Mail Attached.

[Endorsed]: Filed October 20, 1949. [172]

[Title of District Court and Cause No. 10391-PH.]

ANSWER OF HUDSON PRODUCTS COMPANY, A CORPORATION; HUDSON PRODUCTS COMPANY, A CORPORATION DOING BUSINESS AS MAYWOOD PHARMACAL COMPANY, AND ALLEN H. PARKINSON, AN INDIVIDUAL

The defendants, Hudson Products Company, a corporation; Hudson Products Company, a corpora-

tion doing business under the fictitious firm name of Maywood Pharmacal Company, and Allen H. Parkinson, an individual, by way of Answer to the Complaint for Injunction filed herein admit, deny and allege as follows:

I.

Answering the allegations of Paragraph 3 of said Complaint these answering defendants admit that Hudson Products Company, a corporation, and Hudson Products Company, a corporation doing business under the fictitious firm name of Maywood Pharmacal Company, are distributors of certain male hormone drugs; that said male hormone drugs consist of methyl testosterone linguets [183] containing 5-milligrams of methyl testosterone and methyl testosterone linguets containing 5-milligrams of methyl testosterone and a small amount of Vitamin B_1. These answering defendants deny generally and specifically each and every other allegation contained in said Paragraph, and in this connection deny that said defendants or any of them have at any time or at all sold, offered for sale or distributed in interstate or intrastate commerce any female hormone drugs of the kind and character described in said Paragraph or otherwise since on or about July 13, 1949; and deny that they, or any of them, intend to sell, offer for sale or distribute female hormone drugs of the kind or character described in said Paragraph in interstate or intrastate commerce.

II.

Deny generally and specifically each and every allegation contained in Paragraph 4 of said Complaint.

III.

Answering the allegations of Paragraph 5 of said Complaint defendants admit that Hudson Products Company, a corporation doing business under the fictitious firm name of Maywood Pharmacal Company, has since on or about July 13, 1949, circularized former customers of Hudson Products Company, a corporation, offering a revised formula containing methyl testosterone with Vitamin B_1 in linguet form. Defendants attach hereto and incorporate herein by reference as though fully set forth one of said circulars and mark the same as Exhibit "A" hereto. Defendants admit that defendant Hudson Products Company, a corporation, is circularizing and since on or about July 13, 1949, has circularized druggists in the State of California and other states offering Hudson hormones on a wholesale basis. Defendants allege that said last named circulars, among other things, describe the products offered, as methyl testosterone tablets, both with and without Vitamin B_1, and that among other things said circular states [184] "Hudson Products Company, Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drugstore"; and that said circular, among other things, states that "At last, the first Hormones to be labeled for over-the-counter sale." Defendants

attach hereto and incorporate herein by reference as though fully set forth, one of last named circulars and mark the same as Exhibit "B" hereto.

Defendants deny generally and specifically each and every other allegation contained in said Paragraph 5, except insofar as the same is expressly admitted herein.

IV.

Answering the allegations of Paragraph 6 of said Complaint defendants admit that Hudson Products Company, a corporation, did until on or about August 26, 1949, offer for sale and ship in interstate commerce methyl testosterone tablets for sublingual use labeled on the carton and on the bottle as alleged in Paragraph 6 of said Complaint. On or about August 26, 1949, defendant Hudson Products Company, a corporation, in lieu of the labeling described in Paragraph 6 of said Complaint composed a new package with the same labeling described in Paragraph 6 of said Complaint, adding to said product Vitamin B_1, and that said product as relabeled has since said date been offered for sale and shipped and is now offered for sale and shipped in interstate commerce by Hudson Products Company, a corporation doing business under the fictitious firm name of Maywood Pharmacal Company. Said carton does not contain a bottle of said tablets as formerly distributed, but contains cellophane strips containing tablets of methyl testosterone combined with Vitamin B_1. A true and correct copy of the carton label so used by Hudson

Products Company, a corporation, prior to August 26, 1949, is attached hereto, incorporated by reference herein as though fully set forth and marked Exhibit "C." The bottle label so used by Hudson Products Company, [185] a corporation, prior to August 26, 1949, is attached hereto, incorporated by reference herein as though fully set forth and marked Exhibit "D." The label used by Hudson Products Company, a corporation doing business under the fictitious name of Maywood Pharmacal Company, since August 26, 1949, is attached hereto, incorporated by reference herein as though fully set forth and marked Exhibit "E." Except as otherwise expressly admitted herein, defendants and each of them deny generally and specifically each and every other allegation contained in said Paragraph 6.

V.

Answering the allegations of Paragraph 7 of said Complaint defendants admit that defendants Hudson Products Company, a corporation doing business under the fictitious firm name of Maywood Pharmacal Company, do now offer for sale and ship in interstate commerce methyl testosterone tablets containing Vitamin B_1 for sublingual use, labeled as described in said Paragraph 7. Defendants allege that the package or carton in which said product is so shipped, together with the labeling appearing thereon is the same as that contained on Exhibit "E" hereto. Except as otherwise expressly admitted herein, defendants and each of them deny generally and specifically each and every other allegation contained in said Paragraph 7.

VI.

Answering the allegations of Paragraph 8 of said Complaint defendants and each of them deny generally and specifically each and every allegation contained therein.

VII.

Answering the allegations of Paragraph 9 of said Complaint defendants and each of them deny generally and specifically each and every allegation contained therein.

VIII.

Answering the allegations of Paragraph 10 of said [186] Complaint defendants and each of them deny generally and specifically each and every allegation contained in said Paragraph, and in this connection allege that defendants have not, nor have either of them, since on or about July 13, 1949, sold, offered for sale or shipped in interstate or intrastate commerce any of the female hormone drugs described in said Paragraph 10, or any of the other female hormone drugs; and that said defendants do not intend to sell, offer for sale, or ship in interstate or intrastate commerce any female hormone drugs of the kind or character described in said Paragraph.

IX.

Answering the allegations of Paragraph 11 of said Complaint these answering defendants admit that defendant Allen H. Parkinson, an individual, was convicted in the above-entitled Court in case No. 20642, Criminal, on July 13, 1949, of distributing

in interstate commerce male and female hormones misbranded in the Federal Food, Drug and Cosmetic Act. Admit that the hormones involved in said action included methyl testosterone and alpha-estradiol tablets. Deny that the Court in said action in announcing judgment stated the matters and things alleged in Paragraph 11 of the Complaint in this action, and in this connection allege that said Court stated in announcing judgment as follows:

> "As to cases 20596, 20642 and 20608, from the evidence and the weight of the evidence I am convinced, beyond a reasonable doubt, that the indiscriminate distribution or dispensation for use of the drugs Testosterone, Methyl-testosterone, Non-Crystalline Estrone and Alpha Estradiol carried not only a potential but an actual danger of injury to some persons. I am also convinced from the evidence that these drugs do not, other than within a [187] restricted class of cases, produce many or any of the alleviatory and beneficial effects that the labeling given them by the defendants indicate and encourage readers to believe that they will generally produce."

That said Court further stated, in announcing judgment, as follows:

> "Now, it is my construction of those pamphlets, leaflets and circulars enclosed in the packages, by which delivery of sales were made, that they were designed to create a belief

that many persons are deficient in their natural testosterone and that by supplementing it with the drug called under various names, a synthetic testosterone, that much benefit could be derived by the user. I do not mean this to convey the impression that I think the defendants intended any fraud. They may, so far as I know, have been acting in full belief of the merits of the drugs for the purposes they recommended them.

"I don't think there is anything further that I need say in the cases."

X.

Answering the allegations of Paragraph 12 of said Complaint, defendants and each of them deny generally and specifically each and every allegation contained therein.

XI.

Answering the allegations of Paragraph 13 of said Complaint, defendants and each of them deny generally and specifically each and every allegation contained therein.

Wherefore, defendants and each of them pray that plaintiff [188] take nothing by its action and for such other and further relief as may be proper.

HOWLETT AND ELSON,

By /s/ EUGENE M. ELSON,

Attorneys for Defendants.

Exhibit A

Maywood Pharmacal Company
6912 Hollywood Boulevard, Hollywood 28, California

Hormones and Vitamins, Controlled Purity, Insured Safety

Dear Friend

Everybody seems to be talking about hormones these days.

Since the male hormone was discovered a few short years ago there has been a flood of literature on the subject. You've probably read some of the many magazine and newspaper stories or the best-selling book on the male hormone. All of them are fascinating to read, and much of what they say is true. The truth about hormones is more amazing and wonderful than any fiction.

Many people would rather believe rumors than find out the truth. There has been a lot of loose gossip about hormones, especially the male hormone, and we hope you haven't been taken in by false rumors and ill-informed talk. Any new medical discovery that offers so much promise to mankind is bound to be the subject of speculation and gossip.

As one of America's leading distributors of hormone products, we want you to know the truth. We don't want this great discovery to be the subject of snickers or back-room talk. We want the public to know what hormones really will do, and what they won't do, and we don't want anyone to

feel that hormones are an embarrassing or hush-hush topic.

You can find out the truth from a qualified physician who has kept up with the latest developments in hormone research. Then you can order a supply of hormones and give them a fair trial.

The newest Maywood formula combines the Male Hormone with Vitamin B-1 in tablets which are easy and pleasant to take. They are available in the convenient Pocket-Pak in 30, 60 and 180-tablet sizes, with full directions for use. Maywood Hormones are of strict laboratory-controlled potency, and their purity and safety are insured with a leading American insurance company for $100,000.

Because we want you to find out for yourself what hormones can do, Maywood Hormones are sold under an unconditional double-your-money-back agreement which is printed on the enclosed order form. To order, simply fill out the form and return it in the enclosed postage-paid air-mail envelope. Your order will be rushed to you by return air mail.

Sincerely yours,

/s/ WALTER WESTON,

Maywood Pharmacal Company.

Exhibit B

IDEAL SHELF-STOCK PACKAGE

you get . . .

QUANTITY	ITEM	RETAIL
¼ DOZ.	**Male Hormone** *with* **Vitamin B_1** *(Methyl Testosterone) 30 tablets, per pkg. $1.85*	$5.55
¼ DOZ.	**Male Hormone** *(Methyl Testosterone) 30 tablets, per package $1.60*	$4.80
¼ DOZ.	**Male Hormone** *with* **Vitamin B_1** *(Methyl Testosterone) 60 tablets, per pkg. $3.50*	$10.50
¼ DOZ.	**Male Hormone** *(Methyl Testosterone) 60 tablets, per package $3.00*	$9.00
¼ DOZ.	**Male Hormone** *with* **Vitamin B_1** *(Methyl Testosterone) 180 tablets, per pkg. $9.45*	$28.35
¼ DOZ.	**Male Hormone** *(Methyl Testosterone) 180 tablets, per package $7.95*	$23.85
		$82.05

retails at . . .

YOUR COST . . . $54.73

"The undersigned hereby guarantees that no article listed herein is, when shipped by the undersigned, adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, to the extent said act is then effective and applicable, or an article which may not, under the provisions of section 404 or 405 of said act, be then introduced into state commerce."

If your wholesaler does not stock . . .

MAIL ENCLOSED CARD TODAY!

HUDSON HORMONES

Exhibit B—(Continued)

Hudson Products Company

Hormones and Vitamins

1067 East Anaheim Street
Long Beach 13, California

Telephone: Long Beach 7-2585

Dear Sir

Everybody's talking about hormones . . . hormones mean big volume and new profits to all druggists.

What are you doing about hormones?

Hormones are the hottest thing in pharmaceuticals today—they'll soon be bigger than vitamins ever where. There's been a flood of publicity, a best-selling book, dozens of national magazine articles, countless newspaper stories.

Thousands of men and women everywhere are interested in hormones—need hormones—want hormones. They'll buy them wherever they can get them.

Most people don't know where to get them!

That's why Hudson Products Co., Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drugstore. Twenty-five million match books will be circulated in California alone . . . plus newspaper ads and tie-in mats.

Your customers will be looking for Hudson Hormones with added Vitamin B-1. If you don't stock them they'll look somewhere else.

Hudson Hormones sell themselves . . . they're packaged for counter display. Put them out in front and watch 'em move.

Hudson Hormones mean big money to you . . . steady repeat sales . . . new customers. They're a product you can promote!

Don't miss these hormone profits . . . don't wait for your competitors to beat you to the draw . . . call your wholesaler or mail the enclosed card.

Yours for faster profits,

/s/ JOHN HUDSON,

HUDSON PRODUCTS CO., INC.

Cable Address:

HUDPROCO

Reference:

Security-First National

Bank of Los Angeles,

Bixby Knolls Branch

Laboratory Controlled Potency - Nationally Known
Nationally Advertised

Exhibit C

MARYWOOD
PHARMACAL COMPANY
The hormones in this package are of purest laboratory-controlled potency. Marywood Hormones are 20, 40 and 100 tablet packages
30 TABLETS
MALE HORMONE (Methyl Testosterone) combined with VITAMIN B1
Orin
MARYWOOD
PHARMACAL COMPANY
It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.
DIRECTIONS. For use by
CAUTION. The male hormone should not be taken
METHYL TESTOSTERONE combined with VITAMIN B1

Exhibit B—(Continued)

Hudson Products Company

Hormones and Vitamins

1067 East Anaheim Street
Long Beach 13, California

Telephone: Long Beach 7-2585

Dear Sir

Everybody's talking about hormones . . . hormones mean big volume and new profits to all druggists.

What are you doing about hormones?

Hormones are the hottest thing in pharmaceuticals today—they'll soon be bigger than vitamins ever where. There's been a flood of publicity, a best-selling book, dozens of national magazine articles, countless newspaper stories.

Thousands of men and women everywhere are interested in hormones—need hormones—want hormones. They'll buy them wherever they can get them.

Most people don't know where to get them!

That's why Hudson Products Co., Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drugstore. Twenty-five million match books will be circulated in California alone . . . plus newspaper ads and tie-in mats.

Your customers will be looking for Hudson Hormones with added Vitamin B-1. If you don't stock them they'll look somewhere else.

Hudson Hormones sell themselves . . . they're packaged for counter display. Put them out in front and watch 'em move.

Hudson Hormones mean big money to you . . . steady repeat sales . . . new customers. They're a product you can promote!

Don't miss these hormone profits . . . don't wait for your competitors to beat you to the draw . . . call your wholesaler or mail the enclosed card.

Yours for faster profits,

/s/ JOHN HUDSON,

HUDSON PRODUCTS CO., INC.

Cable Address:

HUDPROCO

Reference:

Security-First National

Bank of Los Angeles,

Bixby Knolls Branch

Laboratory Controlled Potency - Nationally Known
Nationally Advertised

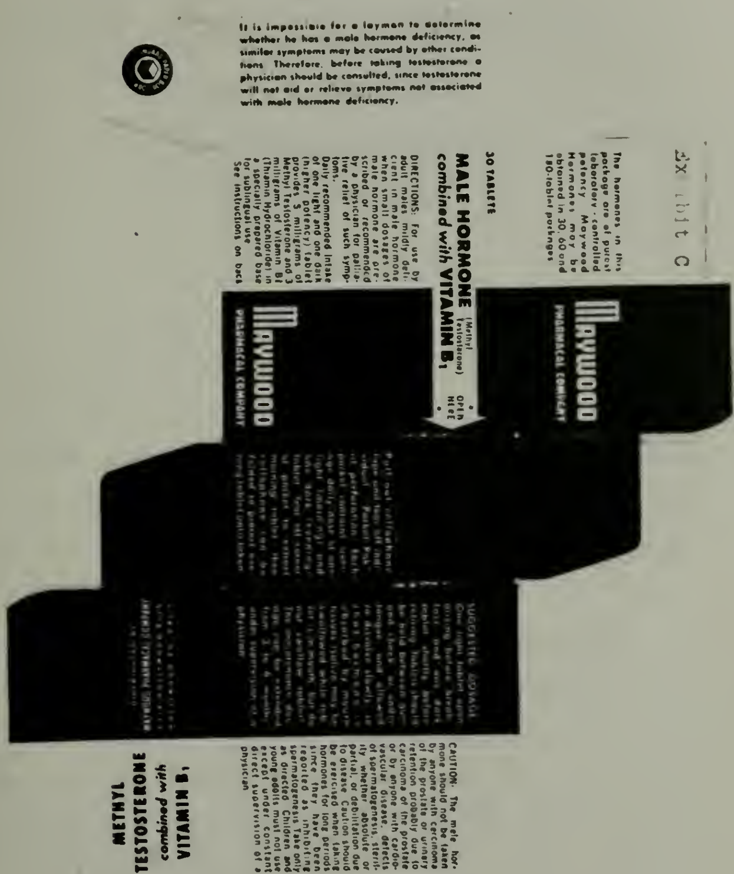
Exhibit C
It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.
The hormones in this package are of purest laboratory - controlled potency. Maywood Hormones may be obtained in 30, 60 and 180-tablet packages
30 TABLETS
MALE HORMONE (Methyl Testosterone)
combined with VITAMIN B1
OPEN HERE
DIRECTIONS: For use by adult males mildly deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.
Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B1 (Thiamin Hydrochloride) in a specially prepared base for sublingual use.
See instructions on back
MAYWOOD
PHARMACAL COMPANY
MAYWOOD
PHARMACAL COMPANY
SUGGESTED DOSAGE
CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.
METHYL
TESTOSTERONE
combined with
VITAMIN B1

Exhibit D

[Center]

[Box Label]

30 tablets 5 mg each

Hudson Hormones for Men

Regular Strength Methyl Testosterone

Hudson Products Co.
Long Beach 5, California

Distributors

[Left Side]

Notice: It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.

Suggested Dosage: One tablet daily shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician.

[Right Side]

Directions: For use by adult males mildly deficient in male hormone when small dosages of male hor-

mone are prescribed or recommended by a physician for palliative relief of such symptoms.

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debiliation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.

EXHIBIT E

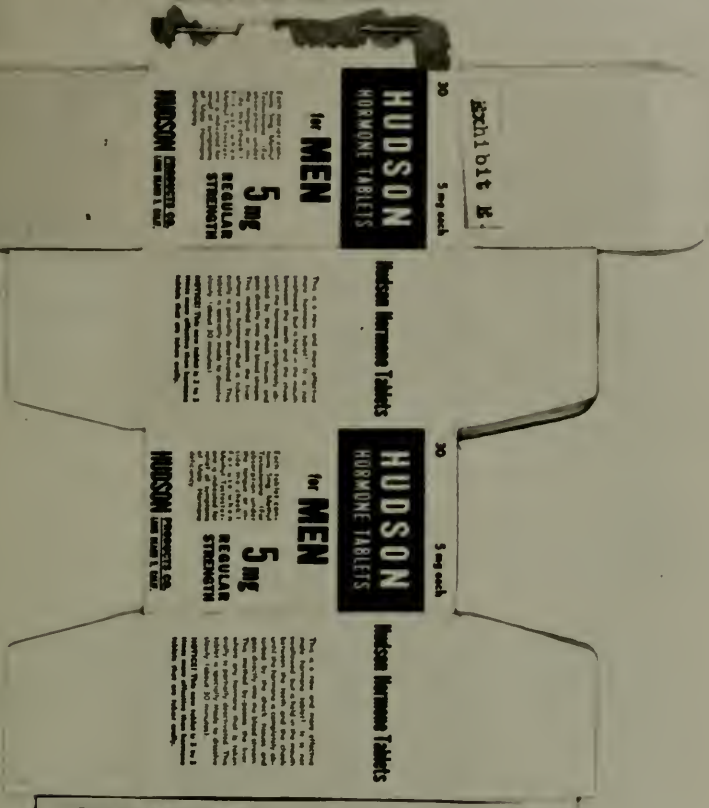

Exhibit E

Duly verified.

[Endorsed]: Filed November 3, 1949.

[Title of District Court and Cause No. 10391-PH.]

AFFIDAVIT OF ALLEN H. PARKINSON

State of California,
County of Los Angeles—ss.

Allen H. Parkinson, being duly sworn, deposes and says:

That he makes this Affidavit in response to certain of the allegations contained in the Complaint for Injunction and the Affidavits of Clinton Hobart Thienes, M. D., Elmer Belt, M. D., Ian MacDonald, M. D., Robert S. Roe, each of which by stipulation of respective counsel herein are deemed to have been filed in this proceeding, and copies of which Affidavits are attached to said Stipulation and are all on file herein.

On or about April 8, 1949 there was filed an Information in the above-entitled Court, No. 20642 Criminal, in which affiant [196] Allen H. Parkinson was named as a defendant. In said Information it was charged that said Parkinson delivered for introduction into interstate commerce certain male hormone drugs and that the same were misbranded in violation of the Federal Food, Drug and Cosmetic Act. The product involved in each Count of said Information involving male hormone drugs, the particulars wherein said products were therein alleged to be misbranded, together with the Sections of the Federal Food, Drug and Cosmetic Act alleged to have been violated, were as follows:

Count I.

(a) Product:

Methyl testosterone tablets, 10 mg. each; oral dosage: 1 daily; in case of male sex hormone deficiency; 3 daily for 10 days, thereafter one per day;

(b) Particulars Wherein Misbranding Was Alleged:

That accompanying said product in interstate commerce was a circular entitled "The Male Hormone." Affiant attaches hereto and marks as Exhibit "A" to this Affidavit a true and correct replica of the circular which accompanied said product.

(c) Violation Charged:

1. Section 502(a), Food, Drug and Cosmetic Act: That the labeling consisting of said circular represented and suggested that said product:
   a. was the true male sex hormone;
   b. with respect to the average man in his late 40's it would stimulate growth and development of the sex organs;
   c. that with respect to the average man in his late 40's it would stimulate growth and development of the male sex characteristics, such as
      (1) distribution of hair
      (2) muscular development
      (3) depth of voice
   d. would correct lack of sexual power and impotence;

e. would relieve and postpone the many conditions associated with middle age;

f. would improve the sense of well-being;

g. would be efficacious in the treatment of
   (1) flushes
   (2) sweats
   (3) chills
   (4) impaired memory
   (5) inability to concentrate on activities tendency to evade them
   (6) nervousness
   (7) depression
   (8) general weakness and lack of physical strength

That the labeling represented by said circular further represented and suggested:

a. that the use of said product would result in improved physical and mental work

b. that the use of said product would exert a tonic action resulting in renewed vigor

c. that said product would impart a better attitude toward social life

d. that said drug would cause nervousness, exhaustion and melancholy to disappear.

That said representations were false and misleading [198] in that

a. said drug would not accomplish the aforesaid purposes.

2. Section 502 (f) (1) Food, Drug and Cosmetic Act: That said drug was further misbranded in that:
   a. the said labeling failed to bear adequate directions for use, in that the directions for use: "Dosage: 1 tablet daily. Important—in case of male sex hormone deficiency take 3 tablets daily for 10 days. After 10 day period take 1 tablet daily," on the labeling were not adequate directions for use.

Count II.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding Was Alleged:

Same as Count I and, additionally, that accompanying said product was a leaflet entitled "The Story of Hormones." Affiant attaches hereto, incorporates by reference herein a true and correct replica of said leaflet "The Story of Hormones" as though fully set forth and marks the same as Exhibit "B" hereto.

(c) Violation Charged:

1. Section 502 (a), Food, Drug and Cosmetic Act; That the pamphlet "Male Hormone" attached hereto as Exhibit "A" represented the matters and things hereto alleged with respect to Count I.

That the pamphlet "The Story of Hormones" represented and suggested

   a. that in the average man said product would

relieve and postpone the many conditions [199] formerly thought to be inevitable with middle age;

b. that said product would be efficacious in:

(1) the treatment of nervous tension
(2) intense subjective nervousness and irritability

c. that said product would be efficacious in the treatment of

(1) numbness in the extremities
(2) itching, prickling and tingling of the skin and waking up at night
(3) headaches.

d. that said product would prevent a decrease in the ability to concentrate

e. that said product would remedy faulty memory

f. that said product would be efficacious in the treatment of depression and melancholia

g. that said product would correct a lack of interest in social and business life

h. that said product would correct a lack of mental concentration

i. that said product would correct a feeling of inadequacy or impotency

j. that said product would be efficacious in the treatment of

(1) hot flashes
(2) feelings of smothering and sweating and chilly, creepy sensations

k. that said drug would prevent the user from tiring easily

l. that said drug would prevent the user from gaining excessive weight [200]

m. that said drug would be efficacious in the treatment of

(1) constipation
(2) vague digestive complaints
(3) precordial, angina pectoris-like pains

n. that said drug would be efficacious in the treatment of urinary symptoms, such as

(1) frequency
(2) nocturia
(3) dribbling
(4) inability to start urinary stream

o. that said drug would restore confidence in mental reactions and decisions

p. that said drug would notably increase the users capacity for mental and physical work

q. that said drug would increase potency and libido.

That said representations were false and misleadling; and that drugs would not accomplish the aforesaid purposes.

2. Section 502 (f) (1), Food, Drug and Cosmetic Act; That said drug was further misbranded in that

a. the labeling failed to bear adequate directions for use in that the directions "Dosage: 1 tablet daily. Important—in case of male sex hor-

mone deficiency take 3 tablets daily for 10 days. After 10 day period take 1 tablet daily" were not adequate directions for use.

Count IV charged: a shipment of female hormones, consisting of alpha-estradiol. An analysis of the charges contained in that Count are not set forth herein for the reason, as alleged [201] in the Answer of the defendants in the present action, said defendants have not shipped in interstate or intrastate commerce any female hormones since the date of Judgment in said Criminal action, July 13, 1949, and do not intend to ship in interstate or intrastate commerce such alpha-estradiol preparations.

No charge was made in said Information that adequate warnings against the use of said products in certain pathological conditions where its use might be dangerous were not contained in said label, and, in fact, on the leaflet attached hereto as Exhibit "A" appeared the statement:

> "The male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate."

On said pamphlet Exhibit "B" hereto "The Story of Hormones" was the warning language as follows:

> "Although both male and female sex hormones are relatively safe to use as a rule, scientific tests prove that they should not be used by anyone suffering from cancer. Neither should they be used by persons suffering from

serious heart trouble. Also, hormone therapy should be used with caution by senile men in whom excessive stimulation of waning sex power may be physiologically undesirable."

Recapitulating the aforesaid charges insofar as the same are material to this litigation, the charges of the Government were that the labeling of said products so shipped constituted a misbranding of said products for the following reasons:

1. That said labeling falsely misrepresented and suggested that said products would be efficacious in the treatment of the conditions enumerated [202] heretofore as to Count I in violation of Section 502(a) of the Food, Drug and Cosmetic Act.

2. That said labeling failed to bear adequate directions for use in that the directions contained on the label of the bottle were not adequate directions for use.

At the outset of the trial of said action, defend- and Parkinson, and affiant herein, took the position and maintained the same throughout that the symptoms referred to in Exhibits "A" and "B" hereto would be relieved if the individual manifesting the same were suffering from a male hormone deficiency, and that said circulars, Exhibits "A" and "B" hereto, did no more than make such a representation, and did not represent that said male hormone products would be efficacious in the treatment or relief of said symptoms if they were caused by some condition other than a male hormone

deficiency. In connection therewith, at the outset of said action, defendant offered to the Court and served a copy thereof upon counsel, his argument in respect thereto entitled "Comparison of Information re Alleged Therapeutic Claims with Labeling Involved (the pamphlets 'Male Hormone' and 'The Story of Hormones')", and said documents so submitted became part of the files and records in said action.

With regard to the charge that the directions for use were inadequate the position of said defendant at the outset of said action and throughout the trial thereof was that said circulars, Exhibits "A" and "B" hereto, suggested the dosage set forth on said labeling and the use of said product only provided that the user was suffering from a male hormone deficiency, and that the information contained in said exhibits was sufficient to enable the average man to determine whether he was suffering from such a deficiency, at least, that he might use the product for a certain [203] period of time and if relieved could conclude that he was, in fact, suffering from such deficiency. That general practitioners, to whom the average individual suffering from such symptoms may go, will invariably prescribe methyl testosterone on more or less a trial and error basis to see whether or not the symptoms complained of are relieved upon use of the product and that if relieved will conclude that the individual was suffering from a male hormone deficiency; and that therefore, in substance, the method employed by the general practitioner in determining

whether methyl testosterone should be prescribed or recommended was and is the same as though the individual tried the product on his own behalf for a certain period of time.

Government Evidence in Support of the Aforesaid Charges

In support of the aforesaid charges, several medical witnesses were called to testify by the Government. References to the reporter's transcript in said criminal action will hereinafter be made for convenience in the event that it should develop that said reporter's transcript should be a part of the record in this case.

I.

Clinton A. Thienes, M.D.

So far as material to this case said witness testified as follows:

That assuming a man to be 50 years of age who complains of flushes, sweats, extreme nervousness, inability to concentrate, nocturia, and he goes to his doctor who is an average general practitioner, and no evidence of cancer of the prostate is diagnosed, he does not believe that the doctor would prescribe methyl testosterone for a period of time and wait and see whether the symptoms were relieved. In his opinion it would not be prescribed by the man's doctor unless there was evidence of the male [204] climacteric, and that the majority of general practitioners would require a laboratory

test as to the secretion of hormones from the testes before prescribing testosterone. (p. 42.)

A person who diagonses his own condition as requiring testosterone probably will not be the type of person who needs it. (p. 62.) Symptoms such as inability to concentrate and irritability in males of approximately 50 years of age are present in conditions other than hormone deficiency. Most of those symptoms are due to something other than such deficiency. They are found in certain types of goiter, fatigue states, anxiety states; in tuberculosis one will find that type of symptom complex. Those conditions would not respond favorably to testosterone. (p. 66.) The only sure way that he knows to determine whether there is a hormone deficiency is by laboratory procedure—and an analysis of the urine. (p. 67.)

II.

Dr. Norris J. Heckel, M.D.

Professor of Urology, University of Illinois

He uses testosterone in urology only for the treatment of men who have a deficiency of the male sex hormone. (p. 159.) Such deficiency is found in endocrine disturbances, best illustrated by eunuchism and by men who have been castrated or whose testes have been injured. (p. 159-160.)

Generally, the symptoms of the male hormone deficiency are impotence, fatigues easily. Male hormone therapy is indicated to stimulate the growth

and development of the sex organs and male sex characteristics such as distribution of hair, muscular development and depth of voice, when that condition is caused by deficiency of the male sex hormone, best illustrated in the eunuchoid individual. (p. 162 and 165.)

Hormone therapy would not correct impotence in a man in his late 40's unless it were due to a male hormone deficiency. (p. 168, 169.) [205]

In his opinion, if a man had a male hormone deficiency, methyl testosterone would correct lack of sexual power and impotence, and would postpone the many conditions associated with middle age and improve the sense of well-being. If a man were suffering from such deficiency, methyl testosterone would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness, and lack of physical strength. (p. 172, 173.)

However, there are many diseases that would produce those symptoms. But if a man were suffering from a male hormone deficiency, methyl testosterone would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor and would impart a better attitude toward social life, and cause nervousness, exhaustion and melancholy to disappear. Those symptoms, however, are also symptoms of other diseases or conditions. (p. 174, 175.) A male hormone deficiency is determined first by a careful history, second, a careful physical examination,

and third, laboratory tests to aid in diagnosis such as the estimation of 17 k*i*tosteroids in the urine, and by the estimation of the excretion of gonadtropins, also in the urine. (p. 176.)

There are no subjective symptoms by which he could correctly diagnose a male hormone deficiency, and the symptoms above described would not indicate, necessarily, a hormone deficiency.(p. 177.) Impotence is not an indication of male hormone deficiency for it may be due to a variety of causes such as syphilis or may be psycho-genic origin, worry, fatigue, mental strain. Impotence comes with age as a natural process. (p. 178.)

In his opinion, if a patient visited a general practitioner complaining of the several symptoms, nervousness, etc., etc., the doctor would make a careful examination of him to see if he could find out what produced the symptoms. He would conduct a complete [206] physical examination from head to foot. If that produced nothing, he would probably examine the urine for sugar. This might give him a clue to diabetes which would produce such symptoms. If he found no sugar, he would determine if there was albumin in the urine or whether the patient was suffering from Bright's Disease or some kidney disturbance. If nothing turned up then, he would take the patient's blood pressure. If that was normal and his urine negative, he would probably take a blood count to see whether the patient was suffering from anemia. There might be some indication that the patient had a gastro-intestinal disturbance, and an x-ray picture of the tract, or

colon, would be taken, or his basal metabolic test to discover whether there was some disturbance of the thyroid. If such doctor found nothing suspicious as the result of such examination, he might, but he shouldn't, suggest testosterone to the man for a period of 4 to 6 weeks to see if those symptoms were relieved. (p. 186-190.)

He, however, has never been able to make a diagnosis of the male climacteric. (p. 191.) There is no question but that in view of the hundreds of thousands of packages of testosterone sold during the year it is indicative of considerable benefit to many, many, many men. (p. 194-195.) He recognizes that some general practitioners are enthused about methyl testosterone and some object to it. (p. 216-217.) A doctor who is administering testosterone to a male patient keeps that patient under regular or perodic examination during treatment; the purpose being to detect any deleterious results that might occur. (p. 219-220.)

III.

Dr. Elmer Belt

Urologist and member of the Belt Urological Group.

(P. 224 and 372.)

He has personally seen or treated patients who have had adverse or injurious results from the administration of the male [207] hormone. (p. 227).

In the case of the ordinary practitioner to whom a patient goes because he wants a general physical

examination, the practitioner is obligated to put his finger in the rectum and carefully feel the prostate. (p. 233, 234.) There are many instances in which methyl testosterone is very valuable. The necessary precautions to its use are tests as follows: (1) rectal examination; (2) determination of the level of acid phosphatase in the bloodstream, and (3) other tests of recent origin. One test of the proteins of the blood which shows the presence of cancer or the absence of it, and another, a blood protein test. He feels that such precautions are a prerequisite to any testosterone therapy except in groups where cancer of the prostate is not liable to occur, and by that he means cases in which it is particularly valuable or the group of young individuals who show a definite endocrine deficiency in regard to testosterone and who need it in the normal process of their growth and development. (p. 246, 247.) By that he is referring to boys who had their testicles blown off during the war, (p. 390) and persons suffering from hypogonadism—persons whose testicles are not performing their proper function, meaning undeveloped testicles and undeveloped genitalia—a young individual whose testicles are not up to standard in size and function. (p. 391, 392.)

The acid phosphatase test, if one is set up for it, can be completed in a few minutes. The 17 ketosteroids test requires approximately a week to complete, and the blood test a very short time. The general practitioner is not equipped to make either of those tests and in fact, his office is not equipped

to make the 17 ketosteroids test, and he is having them made at the California Institute of Technology. (p. 395.) In a person who is apparently normal physically, the examination necessary to determine whether he is suffering from an endocrine deficiency might possibly be the [208] 17 ketosteroids test. (p. 248.) Such examinations require special training. There are no objective symptoms of a male hormone deficiency which a layman could recognize and actually use to diagnose such a condition. He might confuse almost anything with the loss of what he thought was his normal quantity of hormones. (p. 249.) After a careful examination of the patient and no indications of cancer of the prostate being present, it would still be dangerous or conducive to the development of cancer of the prostate for the person to take testosterone. (p. 251-253.)

In his opinion, if a man 45 to 50 years of age visited a general practitioner and complained of sweats, nervousness, did not remember things as he used to, couldn't concentrate on activities, had a tendency to evade them, and the doctor was of the opinion, after learning of these symptoms that testosterone might be of benefit to the patient, he, the doctor, would, before prescribing testosterone, in the first place, think—think about the problem, and if he thought about it very much he probably wouldn't prescribe testosterone for those symptoms because they do not indicate hypogonadism and it is virtually only in hypogonadism that testosterone is effective. (p. 383, 384.) A very careful analysis of

the problem would be needed for that patient and he would be very apt to get it at the hands of an alert general practitioner. (p. 385.) It would be a very loose method of detecting the man's trouble for the general practitioner to prescribe testosterone to such a patient for a period of 3 to 4 weeks to see whether the man had been relieved, for it the doctor really thought about the problem, got down to business and studied it, he would be concerned first about the psychic factors in the individual and whether he was overworked and trouble. (p. 385.) Before prescribing testosterone the general practitioner would certainly make a rectal examination and feel the prostate. As to the blood and urine tests, there would be no blood tests that such [209] doctor need do, unless he wished to do the acid and alkaline phosphatase tests. The urine test would not show him anything unless he wished to take the time to give the 17 ketosteroids test. (p. 385-386.) If he really wanted to find out whether the man had a hormone deficiency, he would give such a test, as well as acid phosphatase test, for cancer of the prostate, (p. 386) and if he used testosterone, then he would see that the symptoms were not relieved. (p. 387.)

The problem of hormone deficiency is the specialty of the general practitioner. The middle aged man who is tired and worn-out and who has come to the doctor for some help is the general practitioner's "meat." (p. 388.)

In the case of the individual who visits the general practitioner who gives him a rectal examination and finds nothing suspicious and prescribes methyl

testosterone, and the patient has the prescription filled, that patient can go back to a drug store as often as he wishes and have that prescription refilled without going to that doctor or to any other doctor and having a new prescription made up each time he wants testosterone. In fact, he doesn't have to have a prescription in the first place. (p. 398.) He can go back and have it refilled as often as he wants without seeing another doctor. (p. 399.)

What he is pleading for in this case is that the requirement be made that the product methyl testosterone be sold only on prescription. (p. 400.)

He does not think that the male has any climacteric, and he believes that most careful observers are of the same opinion. However, that is not an opinion that is universally shared by the profession. (p. 407.)

If the patient comes to him referred by another doctor, he always allows the other doctor the benefit of whatever doubt might exist in his mind, and his tendency is to go on with the [210] original treatment the other doctor has established until he can discuss the problem with him. (p. 436-437.)

IV.

Dr. Charles Huggins, M.D.
Professor of Urology, University of Chicago.

Since 1938 their work has been almost exclusively related to the male hormone and its reaction in normal and cancerous individuals. (p. 256-258.) He does not think that a male hormone deficiency

occurs in quasi-normal individuals—persons who are not hypogonads or who have not been castrated. (p. 260.) He denies that methyl testosterone would have any effect upon the conditions enumerated in the Information. These symptoms are not symptoms of a person who is deficient in male hormones. (p. 272-275.) Because of the toxic effects of the male hormone, he thinks that testosterone should always be administered under the supervision of somebody with some knowledge of such matters. (p. 277.)

In his opinion, if an individual complained to a general practitioner—an all around family doctor —of the symptoms referred to in the Information, some would prescribe methyl testosterone for a period of 4 to 6 weeks, and see whether the symptoms were relieved without going through the elaborate tests described by him—such as blood tests, etc.—but some doctors would not, and he thinks that very few informed physicians would prescribe it under those circumstances. (p. 292.) He doesn't think that the average physician would recognize the symptoms referred to as an indication for sex hormones. The blood test he referred to can only be done in well-established hospitals. (p. 294.) Listlessness, lack of memory, as described in the Information, cannot be helped by the administration of male hormones even if the person was suffering from a deficiency thereof. He doesn't believe that there is such a thing as the male climacteric though there is a difference of opinion

on that subject in medical circles, [211] and there are a great many articles in which the male climacteric is discussed, but he does not share the opinion of those investigators. (p. 303-304.) He is a professional investigator, (p. 311) and eliminating the eunuchoids, castrates and women, he does not think that they have prescribed testosterone in his hospital during the last 5 years. He disagrees with statements concerning the male climacteric by Dr. Hans Lisser and Robert F. Escamilla appearing in Volume 46 of "The Urologic and Cutaneous Review," page 87, February, 1942. (p. 313-315.) He disagrees with statements of Dr. Harry Benjamin on the subject of impotence and its treatment by testosterone appearing in the "Urologic and Cutaneous Review," Volume 50, page 143, March, 1946, and with regard to the article by Dr. August A. Werner, entitled "The Male Climacteric: Additional Observations of 37 Patients," appearing in the Journal of Urology, Volume 49, page 82, June, 1943, he thinks they are absurd and he is in complete disagreement with them. (p. 315-316.)

Affiant has not summarized or narrated the testimony of any of the aforesaid Government witnesses dealing with their view that testosterone may accelerate the growth of carcinoma of the prostate, inhibit spermatogenesis, or cause partial sterility. The reason for this omission is that this affiant was not charged in said Criminal action with failure to adequately warn on his labeling that said product might produce those results thereof, as will be seen from an examination of Exhibits "A" and

"B" hereto. No warning statement on any of said labeling was included having to do with the subject of spermatogenesis or sterility. However, affiant was present at all times during the trial of said action which had been consolidated for trial with the case of United States v. El-O-Pathic Pharmacy, a corporation, Martin A. Clemens, an individual, et al., No. 20596, and was aware that defendants in said action had been charged with failure to contain on their labeling adequate warnings concerning the use of said product in [212] accelerating the growth of an incipient carcinoma of the prostate and the effect of said product upon sterility, and in order to comply in all respects with the contentions of the Government, as evidenced by its expert witnesses on those subjects, relabeled his products in the form and manner set forth in the Complaint for Injunction herein.

Defense Evidence

So far as material to the issues before the Court in this case, the defense evidence in said Criminal action was as follows:

I.

Dr. George E. Fakehany, M.D.

Is a Doctor of Medicine (p. 536) and prescribes testosterone on an average of once a day and has never encountered any adverse results from the use of it. (p. 542.)

He prescribes testosterone for males complaining

of the symptoms alleged in the Information of said Criminal action. (U. S. v. Parkinson.) He usually prescribes a month's supply and tries it for a certain period of time to see whether the person is relieved of the symptoms complained of. (p. 547.) Many are relieved and some not. That is quite a usual procedure in the practice of medicine. (p. 548.)

He does not submit such a patient to the tests referred to by the Government medical witnesses. (p. 553-554.) Those symptoms may or may not be caused by a hormone deficiency. (p. 582.)

II.

Dr. Paul E. Travis, M.D.

Is a Doctor of Medicine (p. 596) and he prescribes testosterone for a person manifesting the symptoms referred to in the Information in the Criminal action. (p. 598.) With some patients for whom he has prescribed testosterone, he found very definitely that the symptoms were relieved. (p. 598, 599, 600.) He does not know of any general practitioner who submits a patient to the [213] tests referred to by the Government witnesses, (p. 602) and has never encountered any adverse results from the administration of testosterone. (p. 604.)

III.

Dr. William A. Swim, M.D.

Is a Doctor of Medicine and has practiced internal medicine in Los Angeles since 1918. (p. 653.)

Was formerly a member of the Board of Medical Examiners of the State of California. (p. 654.)

If a person complained to him of the symptoms described in the Information, he would take a general history, make a physical examination and prescribe testosterone (p. 654), and has done so on many occasions and ever since there has been testosterone on the market. Testosterone in commercial quantities has been available for the last 10 years. On many such occasions he has found the individual's symptoms to be relieved and has never encountered any adverse results. He is familiar with what is known as the male climacteric and the symptoms of a person suffering therefrom are those symptoms referred to in the Information. He does not in his practice submit the patient to the elaborate tests mentioned by the Government witnesses. (p. 653-657.)

IV.

Allen H. Parkinson

Testified as a witness for the defense and stated:

That on June 24th, 1949 (following the date on which Government witness Dr. Elmer Belt testified on direct examination) he went to Dr. Belt's office on Wilshire Boulevard at 10:00 a.m. and asked to see one of the doctors, and was referred to a Dr. Ebert, and told him that he would like some testosterone. The doctor asked him if he had ever taken it before and he replied that he had two years ago in Salt Lake City. That a Dr. Openshaw pre-

scribed some. (p. 696-697.) He stated to said Dr. Ebert that [214] he had trouble with diminishing of the testicles and penis, and the doctor asked him if he was taking it then, and he replied "no," but that he continued taking it at frequent intervals because it had a tonic effect and made him feel better. The doctor asked him if a 50-mg. shot of testosterone propinate would be satisfactory, and he replied that it would. He was then shown to another room, and in a moment a laboratory assistant entered and took a blood sample from him. Then Dr. Belt entered the room, inserted his finger in the witness' rectum, and another technician entered and injected him with testosterone. Said Dr. Belt asked him what he wanted on his prescription—how many tablets he wanted—and the witness replied that he would like 100-mg. linguets of methyl testosterone. Dr. Belt then said "all right" and asked him to urinate in three glasses, which he did, and asked him how he took them, and he replied that he took 3 or 4 a day, and then maybe laid off 3 or 4 days, depending on how he felt, and then resumed. Dr. Belt replied "all right" and "what did the doctor in Salt Lake City charge you?" and the witness replied "$5.00" and Dr. Belt replied "All right, pay the girl $5.00 on your way out." (p. 699-700) and said Dr. Belt wrote out a prescription for 100-mg. linguets of methyl testosterone. (p. 700.)

In addition thereto, said witness testified that on June 30th, 1949, he called at the offices of a Dr. E. A. Gummig in Pasadena (p. 701) and received

a prescription for 100 tablets of methyl testosterone linguets. At no time during his visit to the doctor's office did the doctor lay any hands on him. (p. 701.)

At this point, your affiant alleges that said Parkinson testified as aforesaid on July 7th, 1949, and that on the following day, July 8th, 1949, the said Elmer Belt was recalled to the witness stand by the Government as a rebuttal witness, and testified with reference to the visit to him of said Parkinson that he did see Parkinson on June 24th, 1949; that when he went into the [215] room where Parkinson was, he reviewed the history which the other doctor had taken, that Parkinson told him that he had been receiving a weekly maintenance dose of 50-mg. of testosterone, and in so testifying the doctor testified from notes made in his office during the course of said examination by him and by some of his employees. (p. 825-826.) Parkinson asked for a prescription of 10-mg. tablets or linguets of testosterone to be taken 3 times daily. He does not think he stated that he had been taking that amount. He asked for the injection and said he was going to San Francisco and wanted to have a maintenance dose to take with him. When Dr. Belt entered the room where Parkinson was, he asked him if Dr. Openshaw referred him to them, and Parkinson said "yes." (p. 827.) That two years ago his testicles and penis had begun to atrophy and he became sexually impotent. That Dr. Openshaw of Salt Lake City had been treating him with a weekly maintenance dose of 50-mg. That he had

been away from Salt Lake City for three weeks and that his physician recommended that he come to them for treatment. That he was leaving for San Francisco shortly. Belt made a complete physical of Parkinson, observed his general makeup, his eyes, his pupils, his pharynx, his teeth, felt his thyroid, examined his thorax, took his blood pressure, determined his pulse rate and rhythm, felt of his abdomen, looked at his extremities, tapped his reflexes, examined external genitalia, put a finger in his rectum and examined his prostate and as a result found no contra indications for the use of testosterone. He instructed his technician to take a specimen of his blood and he had already been instructed to urinate in three glasses which he did, and that material was examined. The reason for taking the blood sample was that Parkinson said he intended to return and the doctor wanted to know whether the acid or alkaline phosphatase had changed. (p. 828-829.) Before he began his examination of Parkinson, he told him that they examined people carefully who [216] asked for testosterone or who are getting it, to be sure it isn't doing them any harm. He did not wish to undermine Doctor Openshaw's authority as the man presented himself to him as a transient under the care of another physician, and it would have been poor taste and poor policy and poor judgment as well as poor medicine to interfere with the activities of his own physician. (p. 830.)

The notes of the examination from which the doctor referred disclosed the following:

"Q. Commencing with 'Complain,' 'Testosterone shots only.'

What is that (indicating)?

A. History and physical.

Q. History and physical?

A. Wait a minute. Past history.

Q. What is this?

A. H. P., past history.

Q. Oh, H. P.

A. I guess that is history and present ailment.

Q. H. P. I.? A. History of past illness.

Q. History of past illness. It reads as follows: Two years ago, this man's testicles and penis began to atrophy and he became sexually impotent. Dr. Openshaw of Salt Lake City has been treating him with a weekly maintenance dose of 50 milligram testosterone Neo-Hombreol. He has been away from Salt Lake City for three weeks. His physician recommended that he come here for the same shots. He will be leaving here for San Francisco shortly. Wants oral prescription for Metandren 10 milligram tablets.

On the reverse side, what is this? [217]

A. Ear, nose and throat.

Q. What is this up here (indicating)?

A. Present illness, "P. I.," it looks like.

Q. And something here. "P. I." the doctor says indicates present illness. The nose, ears, eyes and throat, what is that?

A. Tonsillectomy and adenoidectomy.

Q. Tonsillectomy and adenoidectomy. And then over here, "No venereal diseases, no surg-

ery, general health excellent; two children." What is that (indicating)?

A. "Daughter, age 13—and a boy aged 6 and a girl aged 4."

Q. Boy aged 6 and girl aged 4. What is that (indicating)?

A. "Living and well."

(p. 832, line 4 to p. 833, line 15)

and your affiant alleges that nothing on said record of examination disclosed the results of the extended physical examination of said Parkinson which said Dr. Belt testified he had conducted.

With reference to the $5.00 fee which Parkinson had testified he was charged by Dr. Belt, said Belt explained as follows:

"A. If this patient had not been referred to me from another doctor and if this were not a routine thing, a routine procedure, we would have charged him very much more for this entire procedure. Of course, $5.00 wasn't the total charge here. We explained to him that the laboratory test would be $6.50, which he said he would like to have us bill him for to this false address that he gave us. This is a purely courtesy situation here. A patient [218] comes in; he is being treated by another doctor in another city; we do our best to oblige both the doctor and the patient by carrying on the procedure that the doctor feels is indicated. I asked him what Dr. Openshaw charged him for this treatment and he said $5.00. As a matter of fact, $5.00 is close to the cost of 50 milligrams

of testosterone propionate. I don't know actually what the cost is to our office from the pharmacy but it is not under that. We charged him the same thing that his doctor charged him, as a matter of courtesy to that doctor, and we didn't charge him for the physical examination and for the urine analysis; nothing else except for the laboratory test." (p. 835)

V.

Hannah Shinglman

This witness testified as a defense witness that on June 27th, 1949, she called at the Beverly Hills office of the Elmer Belt Urologic Group. (p. 739, 740) That she walked into the office and asked to see Dr. Belt and was informed by the nurse that he was not there. She then asked to see another doctor and was referred to Dr. Letourneau whose name appears on the prescription pad of the Belt Urologic Group (introduced into evidence in said case) as a member of said Group. Said doctor asked her what he could do for her and she told him that she and her husband had been in this locality 6 or 8 months and previously her husband had not been feeling well for the last few years—had been nervous, jumpy and irritable and that they figured he was going through the male change. That a doctor in Chicago had given him some shots; that he had put him on tablets. She showed him an empty bottle which had been a container for testosterone linguets [219] and the doctor then gave her

a prescription for 100 metandren linguets, 25-mg., 1 daily, and her husband was not present at any time. (p. 745-746)

VI.

Hazen S. Parkinson

This witness testified for the defense as follows:

That on Sunday, June 26th, 1949, he arrived in Chicago, and on the following day called at the office of Dr. Norris J. Heckel, one of the Government witnesses heretofore referred to. (p. 753-754) In a few moments the doctor came in and the witness told Dr. Heckel that he wanted to get a bottle refilled. On the label of the bottle was the language, among others: "Metandren Linguets—500." (p. 772) He showed him a prescription that he had from Dr. Openshaw for testosterone by injection, and told the doctor that he was going on a ship and wanted to take them by mouth. (p. 773) The doctor informed him that he had just returned from Los Angeles on a trial and in reply to the question from the witness "Was there anything wrong with taking them, then, that is going to do me any danger? If there is I don't want them," the doctor replied, "Oh, no, I don't know as they will do you any damage, but we don't want them sold over the counter." The doctor took a urine sample and placed his finger up the rectum of the witness, and wrote the prescription for 500 metandren methyl testosterone linguets in the witness' presence. He told the doctor he was going on a ship and that there were 3 or 4 men to a room, and every time

you take a pill, someone else wants one, and he placed upon the prescription a dosage of 1 per day. About 5 or 6 minutes were consumed in this visit with the doctor. (p. 774-775) At the time of this visit the witness was 65 years of age. (p. 776)

Following this testimony, the Government obtained from Dr. Heckel a letter giving his version of this visit which it was stipulated between counsel would be the testimony of said doctor [220] if he were re-called. Said letter alleged that on June 24th, 1949, a Mr. Parkinson came to his office in Chicago and stated that he had been referred by a former patient; Parkinson said that he was 72 years of age, a sailor by occupation and gone from the country for long periods of time; that he was in Chicago as a transient; that his doctor in Salt Lake City had been giving him a prescription for methyl testosterone and that he had been taking this drug under his doctor's direction for the past several years; that he was leaving the country and needed about a year's supply of testosterone and requested a prescription for a year's supply. He showed Dr. Heckel a prescription for testosterone issued by another doctor. Dr. Heckel then made a physical examination of Parkinson, which included a urine analysis and a rectal examination of the prostate and found no contra indication to the use of testosterone; he found that Parkinson's prostate was of normal size, shape and consistency, with no evidence of prostatitis; and that he then renewed Parkinson's prescription for methyl testosterone linguets and advised him to report to his physician at regular intervals.

During the testimony of said Parkinson, affiant herein and defendant in said action sought to elicit from said witness testimony concerning certain general practitioners called upon at random by said Parkinson during the course of said trial, from whom in each instance he obtained prescriptions for methyl testosterone without any examination being conducted. The purpose of said testimony was to dispute the testimony of Government witnesses that general practitioners would not prescribe said drug without elaborate examinations to determine whether or not the individual was suffering from a male hormone deficiency or carcinoma of the prostate was indicated. Said offer of proof was refused but affiant herein alleges that he is now ready and able to prove all of the matters and things embraced in said offer of proof, and [221] therefore alleges that said offer of proof was and is now as follows:

"I also offer to prove that Mr. Parkinson called on several doctors, on the dates mentioned on certain prescriptions, throughout parts of Los Angeles County, and talked at random; that in each instance he went into the doctor's office, told the doctor that he wanted this same bottle, the one he used when he saw Dr. Heckel, refilled, and asked for a prescription; that in each instance he received a prescription for these linguets and on no occasion was anything said to Mr. Parkinson about sterility or fertility or cancer of the prostate, nor did any of the doctors lay a hand on him, and he did not call on

any doctor who turned him down on the request for a prescription.

"The doctors that would be subject to Mr. Parkinson's testimony in that regard would be Dr. G. G. Ferbryck, M.D., 516 Professional Building, 117 East 8th Street, Long Beach, California, who wrote out a prescription for Metandren Linguets, one a.m. and p.m., and the date was June 29, 1949; Dr. Wayne P. Hanson, in the same building, on June 30, 1949, wrote out a prescription for 500 10-milligram Metandren Linguets, directions, one linguet daily; that he also called on Dr. George D. Stilson and Dr. Milo Ellik, together in the same office, 511 Professional Building, 117 East 8th Street, Long Beach, on June 30th, and received a prescription from Dr. Ellik for 500 Metandren Linguets, directions, as directed; that he called on Dr. Raymond W. Kelso on June 30, 1949, the doctor's address being 117 East 8th Street, Long Beach, who wrote out a prescription for 250 [222] 10-milligram Metandren Linguets, with directions, dissolve one on tongue each day; that he called on George B. Hanson, M.D., 716 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, received a prescription for 250 Metandren Linguets, 10-milligrams, directions, one per day; that he called on Dr. H. F. Gramlich on June 30, 1949, address, 117 East 8th Street, Long Beach, and received a prescription for one bottle of metandren linguets, directions, as directed; that he called on Dr. P. W. Prince of the Bishop Clinic staff, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription

for 250 10-milligram Metandren Linguets, directions, I guess it is, one daily, dissolve in mouth; that he called on Dr. L. L. Wiltse, 714 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 500 Metandren Linguets, directions, take as directed; that he called on Dr. Marvin R. Lauer, 829 East Compton Boulevard, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, 10-milligrams, directions, use as directed; that he called on Dr. Francis J. Ort, 107 North Santa Fe Avenue, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, directions, two daily; that he called on Dr. L. C. Lowe, 706 South Hill Street, Los Angeles, on July 1, 1949, and obtained a prescription for 500 Metandren Linguets, 10-milligrams, directions, as directed; that he called on Dr. Glenn E. Jones, 403 West 8th Street, Los Angeles, on July 1, 1949, and received [223] a prescription for 500 Metandren Linguets, 10-milligrams, directions, one or two per day; that he called upon Dr. R. L. Byron, 1015 Chapman Building, 756 South Broadway, Los Angeles, on July 1, 1949, and received a prescription for 500 Metandren Linguets, 10-milligrams, directions, one as directed. (p. 764-767)

The Re-Labeling of Said Products Subsequent to the Aforesaid Judgment of Conviction

Immediately following the judgment of conviction in said criminal action, affiant consulted with expert counsel in labeling matters and legal counsel on the subject of re-labeling said product so as to conform

to the objections made by the Government and disclosed by Government evidence in said criminal action. In so doing, affiant had in mind that said Government witnesses, with the sole exception of Dr. Charles Huggins, had testified that methyl testosterone was of great value in relieving the symptoms referred to in the Information in said criminal case provided that the individual was suffering from a male hormone deficiency; and that said symptoms might, however, be caused by conditions and diseases other than a male hormone deficiency, and that only a doctor could correctly diagnose the condition.

Your affiant was well aware of the allegations in the Information, entitled United States of America v. El-O-Pathic Pharmacy, et al., No. 20596, in which Martin A. Clemens was likewise a defendant, charging that the labeling there failed to warn the user that methyl testosterone might accelerate the growth of an incipient carcinoma of the prostate and might cause sterility. Affiant alleges that in said criminal Information, so filed against El-O-Pathic Pharmacy, et al., the term "carcinoma of the prostate" was employed as distinguished from "cancer of the [224] prostate." Therefore, and notwithstanding the fact that in the criminal action filed against your affiant no charge was made that the warning statements contained on his label and represented by Exhibits "A" and "B" hereto, did not constitute adequate warnings, nevertheless, for the protection of the public and to warn the user in a manner consistent in all respects to meet the objections of the Government in the criminal action against El-O-Pathic,

your affiant with the aid and assistance of expert counsel aforesaid, revised said warning statement in the manner and form displayed upon the labeling and set forth more fully in the Complaint herein. In all other respects the labeling formerly employed by affiant was entirely discarded and entirely redrafted. In order to eliminate the objections of the Government that said product should not be continued over a period of time unless under the supervision of a physician, in that sterility might be caused thereby or a carcinoma of the prostate might be accelerated in growth thereby, affiant caused to be placed on said label, among other things, language to the effect that said product should be taken, 1 tablet upon arising before breakfast, or 1 tablet shortly before retiring, and that "the maintenance dosage can be extended from 3 to 6 months under the supervision of a physician. (Emphasis added.)

In order to overcome the objections made by the Government in said criminal action that an individual layman could not diagnose his need for said product, affiant caused also to be placed upon said label directions as follows:

"For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician, for palliative relief of such symptoms." (Emphasis added.)

As a further caution to users of said product that a physician should be consulted for the purpose of determining [225] whether or not the symptoms manifested were the result of a male hormone deficiency, and further, explanatory of the label lan-

guage above referred to that the product was to be used when "prescribed or recommended by a physician," affiant caused to be added to said label the following:

> "It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted since testosterone will not aid or relieve symptoms not associated with male hormone deficiency."

During the course of the said criminal action, as part of the Government's evidence directed against the defendants El-O-Pathic Pharmacy, and Martin A. Clemens in case No. 20596, some witnesses for the Government testified that should testosterone be taken by young men who are desirous of stimulating their sexual desire and ability it might result harmfully to them unless under the guidance of a physician. Therefore, in order to meet said objections, affiant caused to be placed upon said label the following:

> "Children and young adults must not use except under constant direct supervision of a physician." (Emphasis added.)

In order to meet the objections of the Government and the testimony of witnesses produced by the Government in said criminal action in the case of United States v. El-O-Pathic Pharmacy, et al., Claim No. 20596, that the labeling involved therein did not contain adequate warnings against the use of said

product when carcinoma of the prostate was indicated and without adequate warnings of the use of said product might cause sterility, affiant caused to be placed on said labeling the following cautionary [226] language, and discarded the cautionary language formerly employed by him and contained on Exhibits "A" and "B" hereto (to which no objection was made in said criminal action):

> "The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate, or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed." (Emphasis added.)

In response to the allegations contained in the Complaint for Injunction herein, and the Affidavits filed in support thereof, that 5-milligrams of methyl testosterone has no therapeutic value, affiant alleges as follows: that the United States Pharmacopoeia lists the dosage of methyl testosterone to be:

> "Average dose, sublingual, 5-milligrams"

That the American Medical Association, in the 14th Edition of "Useful Drugs, 1947" lists under methyl testosterone the following:

> "Dosage: average dose, sublingual, 5-milligrams"

That the American Medical Association in its publication "Epitome of the Pharmacopoeia of the United States" and the "National Formulary, 8th Edition," list under methyl testosterone the following:

> "Sublingual, 5 milligrams, Methyl testosterone usually available in tablets containing these amounts."

In addition thereto the witness Hazen S. Parkinson in the aforesaid criminal action instituted and tried against affiant [227] as aforesaid, testified that when he called upon the Government witness Dr. Norris J. Heckel he requested and obtained from said witness a prescription for 500 Methyl Testosterone Linguets, each containing 5-milligrams of methyl testosterone, and the directions upon said prescription, so written by said Government witness, Dr. Norris J. Heckel, directed said Parkinson to take one of said linguets per day.

Your affiant further alleges that in said criminal action, United States v. El-O-Pathic Pharmacy, et al., No. 20596—Criminal, there was involved in Counts XII, XIII and XIV thereof, linguets each containing 5-milligrams of methyl testosterone, but that no charge was made in said Information or otherwise during the course of said trial that said linguets contained no more than 5-milligrams of methyl testosterone had no therapeutic value.

Affiant further alleges that for approximately the 18 months preceding the institution of said criminal action against him in April, 1949, he consistently sold, offered for sale and shipped in inter-

state and intrastate commerce methyl testosterone containing no more than 5-milligrams per tablet or linguet but that no charge was made in said criminal action instituted against him, nor has any been made until the filing of this action that 5-milligrams per day of said product had no therapeutic effect. Your affiant alleges that he had shipped said product containing no more than 5-milligrams for said period of time (18 months) and that during said period your affiant had handed to inspectors of said Food and Drug Administration, who called at his place of business, samples of said 5-milligram product, and all of this long prior to the institution of said criminal action and during the time that the shipments charged in said criminal Information, United States v. El-O-Pathic Pharmacy, et al., No. 20596, against him took place.

Your affiant further alleges that he is informed and [228] believes and therefore alleges that the law of the State of California does not, nor does any United States statute or rule or regulation of any administrative agency thereof require that methyl testosterone in linguet or tablet form be sold only by prescription of a physician. That notwithstanding said fact the said Food and Drug Administration of the United States Government will not approve any labeling of such product for sale without prescription regardless of the warnings contained thereon, and regardless of the fact that the labeling does, as does the labeling subject of this Complaint, repeatedly advise the user against the use of said product except upon recommendation and under the supervision of said physician.

In addition thereto your affiant alleges that an inspector of the Food and Drug Administration, working out of the Los Angeles station and whose last name is Woussatt, stated to your affiant at affiant's place of business, 1067 East Anaheim Street, Long Beach, California, that the only labeling of methyl testosterone that would meet with the approval of the Food and Drug Administration was a label which contained the statement:

> "Caution: to be dispensed only by or on the prescription of a physician."

and that regardless of the extent or content of the labeling employed and accompanying such product the Food and Drug Administration would never permit the said product to be sold over-the-counter and not on prescription.

Subsequent to said Judgment in said criminal action on July 13, 1949, affiant completely revised the labeling of said product as hereinbefore alleged and on or about September 1, 1949, affiant mailed circulars to retail druggists in California and other states throughout the United States soliciting their business for the purchase by them from affiant of said methyl testosterone so re-labeled, as aforesaid and as more fully set forth [229] in the Complaint for Injunction herein. In connection with such circularization, thousands of said circulars were mailed to retail druggists doing business solely within the state of California. Your affiant is informed and believes and therefore alleges that many, if not the majority, of said druggists doing

business in California are members of the Southern California Pharmaceutical Association, Ltd., and requested advise from said Association whether said product might be sold by them over-the-counter without a prescription.

Your affiant is further informed and believes and therefore alleges that said inquiry was prompted by reason of the fact that following the conclusion in said criminal action some articles appeared in national and local drug journals advising of the outcome of said action and stating that as a result thereof said product could not be sold except on prescription; that on receipt of said inquiries from said druggists said Southern California Pharmaceutical Association, Ltd. on or about September 15, 1949, addressed a letter to Robert S. Roe, Chief of the Los Angeles District of the Food and Drug Administration, and which letter in words and figures was as follows:

"Robert S. Roe, Chief, Los Angeles District,
Food and Drug Administration,
1401 So. Hope Street,
Los Angeles, California.

"Dear Mr. Roe:

"Enclosed herewith are advertising folders that have been distributed to Pharmacists throughout Southern California. Our members have forwarded them to us with the question, 'Can we sell them over the counter' without becoming subject to prosecution by the Federal Food & Drug Administration? [230]

"We are at a loss to know just what to tell them as we were under the impression Hormones had been ruled unsafe for self-medication.

"I would appreciate an opinion from your office regarding this practice.

"Respectfully,

"GEORGE O. BAIRD,
"Executive Secretary."

That within a few days after receipt of said letter said Roe addressed a reply, as follows:

"Dear Mr. Baird:

"I have your letter of August 29, transmitting copies of advertising folders that have been distributed to Pharmacists throughout Southern California. This material offers Hormones for over the counter sale and you request my comment on the application of the Federal Food, Drug and Cosmetic Act.

"It is our view that products containing significant amounts of hormones are not suitable for over the counter distribution, because adequate directions for use and adequate warnings can not be devised that will enable the safe and effective use of such products by the lay person. Consequently, such preparations should be reserved for prescription use. The over-the-counter sale of such products received in interstate commerce would constitute a violation of the Federal Act.

"It is our view that products containing Therapeutically insignificant amounts of hormones would

be worthless and labeling [231] representing them as hormone preparations or as preparations intended for use in treating hormone deficiencies would be misleading.

"Very truly yours,

"ROBERT S. ROE,
"Chief, Los Angeles District."

Affiant alleges that thereafter said Southern California Pharmaceutical Association, Ltd., forwarded copies of said exchange of correspondence to all of its member retail druggists, and thereafter said exchange of correspondence appeared in national and local drug journals.

Your affiant is informed and believes and therefore alleges that said Food and Drug Administration has formed a policy to prevent the sale of methyl testosterone except upon prescription; regardless of the fact that there is no statute, rule or regulations preventing the sale except upon prescription; that said Food and Drug Administration intend to continue to harass, annoy and oppress your affiant by vexatious litigation in order that this policy may be carried into effect, and it is hoped that affiant find himself no longer financially able to continue; that said letter of said Robert S. Roe was calculated and intended to destroy affiant's outlets during the pendency of this litigation, notwithstanding the fact that any or all transactions had or contemplated between affiant and the druggists in the State of California would be intrastate

transactions and wholly removed from the jurisdiction of the Federal Food and Drug Administration.

Your affiant alleges that, as disclosed by said reply of Robert S. Roe, there is no intimation or suggestion that the question which is the subject of his letter is now and was at that time involved in litigation before this Court.

/s/ ALLEN H. PARKINSON.

Subscribed and sworn to before me this 3rd day of November, 1949.

[Seal] /s/ EUGENE M. ELSON,
Notary Public in and for
Said County and States.

Exhibit A

The Male Hormone

The discovery of the Male Sex Hormone is one of the achievements of modern medicine on which the public is comparatively uninformed. Yet it is truly a tremendous accomplishment.

Prof. Ruzicker, a Swiss chemist, succeeded in making Testosterone, "the most potent male hormone" by synthetic means; and for this he received The 1939 Nobel Prize in Chemistry.

"Science is unlocking the secrets of Male and Female sex hormones. Years of scientific effort and research have established that these hormones accomplish many things which up to a few years ago were thought to be impossible. These discoveries are far-reaching and assisting millions of men

and women to lead happier lives, and are helping to relieve some of the many conditions associated with middle age. [233]

Male Hormone Deficiency

The average man in his late forties begins to enter what is called the "Climacteric" period of which time the body undergoes a radical change. Although most of these changes may start during middle age, they may also show up at almost any time. As a rule there may be flushes, sweats and chills. Lack of sexual power, impaired memory, irritability, inability to concentrate on activities or a tendency to evade them, nervousness, depression, general weakness and poor physical strength are some of the major signs which are associated with this declining period.

Impotence

Lack of sexual desire and inability to perform the sexual act is one of the most common complaints of the male "climacteric." When due to deficiency of the male sex hormone, these conditions usually respond to male hormone therapy, which assists in restoring sexual desire and ability to fulfill it. In addition to helping re-establish potency, the male sex hormone helps to relieve other conditions which frequently occur during this period. [234]

Results from Male Hormone

These social, sexual, physical and mental conditions may be relieved by the use of the male sex

hormones, which sometimes bring about startling changes. At first, it may be noticed there is a marked improvement in physical and mental work and a tonic action resulting in renewed vigor. A better attitude towards business and social life is frequently observed. Nervousness, exhaustion and melancholy may disappear and in the large majority of instances the improvement may persist over a long period of time.

Many excellent Reports for the Non Professional layman have already appeared in the following publications:

Readers Digest by Paul de Kruif, July, 1944—August, 1946.

Newsweek, March, 1943.

Time, May 28, 1945.

Newsweek, May 28, 1945.

Liberty, February 2, 1946.

Paul de Kruif's sensational book, "The Male Hormone."

Double Strength

Just One Tablet a Day

30 Day Supply.....$10.00
90 Day Supply..... 30.00

Regular Strength

30 Day Supply.....$ 5.00
90 Day Supply..... 15.00

Mailed in Plain Package

Send Check or Money Order

C.O.D.'s Accepted—Plus Postage

All Orders Sent Airmail
Same Day Received

Hudson's
Multi Vitamin Tablets

At amazing savings, Hudson leads the way in supplying the vitamin needs of millions. Our multi vitamin tablets, at a price within reach of all, now include Folic Acid, the amazing new blood-building discovery for the growth of red blood cells.

Here combined in one small capsule, you get Ten Vitamins, including the sensational new vitamin Folic Acid, which has stirred the medical world and marks the greatest advance in blood-building since the discovery of liver.

Nowhere in America will you find so reasonably priced, such unitage in a single tablet. No matter what vitamins you have used or how much you have paid for them, you should test the benefits of this new multi vitamin now.

Multi vitamins are especially recommended while taking hormones.

You Need Take Only 1 Tablet Daily

Each tablet contains:

Vitamin A (Fish Liver Oils)	5,000 I.U.	125% MDR
Vitamin D (Irrad. Ergosterol)	500 U.S.P.	125% MDR
Vitamin B_1 (Thiamin)	3.0 Mg.	300% MDR
Vitamin B_2 (Riboflavin)	2.0 Mg.	100% MDR
Vitamin B_6 (Pyridoxine)	0.5 Mg.	*
Vitamin C (Ascorbic Acid)	30.0 Mg.	100% MDR
Calcium Pantothenate	5.0 Mg.	*
Niacin	10.0 Mg.	*
PABA	1.0 Mg.	*
Inositol	1.0 Mg.	*
Choline	5.0 Mg.	*
Folic Acid	0.05 Mg.	*

MDR—Minimum Daily Requirement

* —Minimum Daily Requirement Not Known

Hudson's Multi Vitamin Tablets

(100-Day Supply) $4.95

The Female Hormone

(E Estradiol)

The use of Female sex hormones usually brings prompt relief from such symptoms as hot flashes, emotional disturbances and other manifestations associated with the menopause. A steady readjustment may be obtained from the use of hormones,

which help to overcome most menopausal conditions in women approaching or passing through this period.

Double Strength

30 Day Supply.....$10.00
90 Day Supply..... 30.00

Regular Strength

30 Day Supply.....$ 5.00
90 Day Supply..... 15.00

Mailed in Plain Package

Send Check or Money Order

C.O.D.'s Accepted—Plus Postage

All Orders Sent Airmail
Same Day Received

Relatively Safe

The Male and Female sex hormones as a rule are relatively safe to use; however, they should be used cautiously by some individuals. The Female sex hormone should not be used by women with cancer or pre-cancerous lesions of the breast or genital organs and should be used with care by women with a family history of frequent incidence of breast or genital cancer. The Male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate.
Caution: Take only as directed.

Hudson Products Co.
341 Harding St.
Long Beach 5, Calif.

Hudson Products Company
341 Harding St., Long Beach 5, Calif.

Gentlemen: Please rush my order via first class mail today.

No. Desired Amount

Bottles of Hudson Multi Vitamin Tablets (100 tablets) .....$4.95 .....
Total .....

I am enclosing cash.... check.... money order.... C.O.D.....

Name .....
Address .....
City..... Zone.... State.....

All Hudson products are sold on a money back if not satisfied agreement. [235]

Exhibit B

The Story of Hormones

Hudson Products Company, Long Beach, Calif.

Index

The Story of Hormones

How It All Began . . .

Far-reaching discoveries about male and female sex hormones are among the important achievements of modern medicine on which the general public is comparatively uninformed. Yet recent scientific research has established beyond doubt that treatment with hormones can bring about human benefits believed impossible until a few years ago.

As a result of incessant experiments with first the male and then the female hormones, science today assists millions of men and women to lead happier lives. Many conditions formerly thought to be inevitable with middle age can now be relieved.

For years certain scientists experimented with

extracts and compounds of the sex hormones without satisfying results. Then, in 1935, came the first real step toward today's tremendous accomplishments with hormones—the isolation of a crystalline potent androgen from a bull's testes by a man named Laquer and his associates in Amsterdam. Laquer called the new substance "Testosterone." Today methyl testosterone is recognized as the most potent form of the male hormone.

Following Laquer's discovery a Swiss chemist, Prof. Ruzicker, succeeded in making testosterone by synthetic means. Ruzicker's work confirmed the structure of natural testosterone and won him the 1939 Nobel Prize in Chemistry. Androgenic (male hormone) therapy was thus removed from the realm of speculation and the unbiased scientific study of the physiologic and therapeutic activity of the sex hormone began in earnest.

How Hormones Affect Physical Development and Processes

From puberty to late middle life, and sometimes even in old age, the testes (stimulated by the anterior pituitary gland) produce appreciable amounts of the male sex hormone. Absorbed into the blood stream, which carries it to all parts of the body, the male sex hormone has a variety of functions. For convenience they may be divided into four groups:

1. Influence on male reproductive organs
2. Influence on secondary sex characteristics
3. Influence on other endocrine glands
4. Influence on other organs, tissues and metabolic processes [238]

How Hormones Affect Male Reproductive Organs

The primary function of the male sex hormone is to regulate development and growth of the male reproductive organs. Even before a child is born, male sex hormone production is stimulated by the anterior pituitary gland of the mother-to-be, thus exerting its effect on the fetus.

Proper growth during puberty of the penis, scrotum, prostate, seminal vesicles, and Cowper's gland depends upon the presence of the androgenic (male) hormone. It may also be responsible for early descent of the testes. The male reproductive organs cannot function properly even after full development without an adequate supply of the male sex hormone. Sexual desire and potency are entirely dependent upon the amount and activity of the hormone.

How Hormones Affect Secondary Sex Characteristics

An increase of the androgenic hormone during puberty promotes development of secondary sex characteristics. Accordingly, in men, facial and pubic hair appears. The masculine type of skeleton and muscles develop. Fat deposits are distributed in such a way as to form the masculine type figure. The voice deepens, and the masculine behavior pattern of aggressiveness, vigor, and self confidence also becomes evident. It is interesting to note that marked muscular development has been pro-

moted in animals and in men by the therapeutic administration of the male sex hormone.

Concerning Male Disorders

The Male Climacteric or "Change of Life"

The climacteric in women is clearly defined because of cessation of menstruation. Since men do not menstruate, it was assumed for a long time that they did not have a climacteric. The male climacteric develops gradually, progresses slowly, and may occur relatively early or late in life. Thus it often represents a complex and confusing diagnostic problem.

During this transitional period of involuntional gonadal changes, some men are subject to a variety of distressing and discouraging complaints which may seriously interfere with their capacity for work or enjoyment of leisure. Symptoms which are troublesome in one patient may be entirely absent in another, and concomitant complaints of non-hormonal origin may add to the diagnostic difficulties of a particular case.

Although manifestations of the male climacteric are most frequent in patients in their forties and fifties (the average age in women is 40.8), the possibility of hormonal imbalance must not be overlooked in younger men. Cases in the fourth and seventh decades of life are by no means uncommon. For men from 50 to 65 who complain of vague and often apparently unrelated symptoms (and who under careful study reveal signs of the climacteric) use of methyl testosterone has been urged. [239]

Symptoms of the Male Climacteric

The discomfort men suffer during the climacteric results principally from subjective rather than objective symptoms. These symptoms are classified as (1) nervous, (2) circulatory, and (3) general.

Nervous Symptoms

Practically all patients who can be considered to be suffering from this condition have a feeling of nervous tension or "intense subjective nervousness." There is "inward tremulousness" which is aggravated by fatigue or excitement. Many are nervous and irritable to the extent that they are exceptionally hard to get along with. Ordinarily small mishaps, arguments and annoyances which are normally of little importance occasion considerable nervous and mental disturbance. Many patients complain that they wake up at night and find their hands and arms, or feet and legs, numb. There may also be itching, prickling, or tingling of the skin. Headaches of the non-migrainous type often occur. The two types of headache which are most important from a diagnostic point of view are (1) those in which there is a feeling of great weight upon the head or a feeling of pressure; and (2) those in which the pain may radiate to the neck over the back of the shoulders and down the spine. The latter type headache may last from a few hours to several days, often causing the patient to complain of a mental haziness for days.

A decrease in the ability to concentrate and faulty

memory is frequently complained of, and depression or melancholia are often encountered. Intellectual changes in male climacteric patients have been described as "lack of interest in social and business life, lack of mental concentration and energy . . . a feeling of inadequacy or impotency. Occasionally the individual conceives himself to be useless, hopeless and burdensome."

Circulatory Symptoms

Hot flashes occurred in about a third of recent case studies. They are usually of short duration but are very uncomfortable and patients sometimes compare them to feelings of smothering. They may be accompanied by sweating and chilly, creepy sensations.

General Symptoms

This group of symptoms includes tiring easily, decrease in potency and libido, constipation and the tendency to gain excessive weight.

Vague digestive complaints and precordial, angina pectoris-like pains may also be outstanding symptoms. Urinary symptoms, such as frequency, nocturia, dribbling and inability to start urinary stream are invariably associated with changes in the prostate and seminal vesicles.

Treatment for Male Climacteric

The gratifying effectiveness of replacement therapy with male hormones in the male climacteric has been confirmed by a large number of observers.

Adequate hormone therapy produces in many cases "genuinely desirable results." Patients who have feared they might be mental cases because of depression and nervous instability gradually regain confidence in their mental reactions and decisions. Patients usually report that they regain their grip on life shortly after the start of treatment, and their capacity for mental and physical work is often notably increased. [240]

Impotence

As has already been mentioned, decreased sexual desire or complete impotence may accompany the male climacteric, though it may occur also at other times. Indeed, adequate sexual competence depends upon the integrated co-operation of several factors. Anatomic, hormonal, neurologic, psychologic, and emotional components are involved in the attainment of full potency. Impotence may be caused by a disturbance of one or several of these factors.

When impotence is caused by male sex hormone deficiency, replacement therapy with methyl testosterone is indicated. In most cases this will restore sexual desire, potency and genital tract tone with adequate sexual competence. At the same time there is often an improvement in physical and mental mal-conditions. Methyl testosterone is especially beneficial in young and middle aged men with diminished potency, who were formerly normal.

The Female Hormone

Women, too, can find extraordinary benefits in the therapeutic administration of the sex hormone. Prompt relief is obtainable from such unpleasant menopause disturbances as hot flashes, emotional upsets and other "change of life" manifestations. A steady readjustment may occur through the use of the natural hormone, which helps overcome most menopausal conditions in women approaching or passing through this period.

Hormonal Treatment for Breast Development

Small or undeveloped breasts are frequently a cause of worry to some women. In the form of a specially prepared and medically approved ointment, the female sex hormone used for therapy produces a direct action on the mammary gland. Applied directly to the breast, this hormonal ointment stimulates growth considerably, yet helps retain the pointed shape of the young breast. The desired stimulation results from a re-vitalized concentration of the sex hormone in the body tissue. Marked results are obtainable after 60 to 90 days use.

25 Day Supply of Ointment
(125,000 International Units).....$12.95

2½ Month Supply of Ointment
(375,000 International Units).....$33.95

Warning:

Although both male and female sex hormones are relatively safe to use as a rule, scientific tests prove that they should not be used by anyone suffering from cancer. Neither should they be used by persons suffering from serious heart trouble. Also, hormone therapy should be used with caution by senile men in whom excessive stimulation of waning sex power may be physiologically undesirable. [241]

New Low Prices

The Male Hormone

30 day supply..... 10.00
90 day supply.....30.00

The Female Hormone

30 day supply.....$ 5.00
90 day supply..... 15.00

Mailed in plain package Air Mail same day order received. Send cash, check or money order.

C.O.D. you pay postage.

Hudson Products Co.
341 Harding St.
Long Beach 5, Calif.

Rceipt of copy acknowledged.

[Endorsed]: Filed November 3, 1949. [242]

[Title of District Court and Cause, No. 10391-PH.]

AMENDMENT TO THE ANSWER

As a Separate Affirmative Defense Defendants Allege:

I.

That for some time last past and now the Food and Drug Administration of the Federal Security Agency of the United States Government has interpreted, applied and enforced and does now interpret, apply and enforce Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act in an arbitrary, capricious and unlawful manner, wherein and whereby defendants herein are deprived of their property and liberty without due process of law in violation of Article V of the Amendments to the Constitution of the United States in the following particulars:

That officers, agents and representatives and employees [246] of said Food and Drug Administration of the United States Government have uniformly enforced, applied and interpreted Section 502(f)(1) of said Food, Drug and Cosmetic Act to mean that the term "adequate directions for use" as used in said Section enables and empowers them to decide and determine whether a particular drug and particularly methyl testosterone sold by defendants should or should not be sold over the counter to lay-persons regardless of the statements and contents of the labeling thereon; that should

said officers of said Administration determine and decide that a particular drug and particularly methyl testosterone sold by the defendants should not be sold except on the prescription of a physician, no directions for use for sale of said product over the counter to lay-persons can be adequate and that the only manner in which, under such circumstances, the requirement that "adequate directions for use" be provided on the labeling is to provide thereon that said product should be sold only by or on the prescription of a physician. Notwithstanding the fact that there exists no act of Congress or rule or regulation by any Federal administrative body or tribunal prohibiting the sale of said product except on prescription.

By reason of said arbitrary, capricious and invalid interpretation of said statute applied and enforced by said Administration and the officers, agents and employees thereof defendants are not nor are any of them enabled to know whether at any time any drug product sold by them is or is not in the opinion of said Food and Drug Administration a product which may be sold over the counter to lay-persons regardless of the statements and contents of the labeling thereon or should be sold only on the prescription of a physician.

By reason of said interpretation, application and enforcement of said statute defendants herein are subjected to possible prosecution under said Federal Food, Drug and Cosmetic [247] Act at each time a shipment of a drug product is made in inter-

state commerce, depending entirely upon the whim, opinion, decision or belief of said Food and Drug Administration rather than upon the provisions of said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act.

By reason of said interpretation, application, and enforcement of said statute as against these defendants they are deprived of their liberty and property without due process of law in violation of Article V of the Amendments to the Constitution of the United States.

II.

Defendants further allege that should said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act, properly interpreted, empower said Food and Drug Administration to apply and enforce said Section as hereinbefore alleged, then said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act constitutes an invalid delegation of legislative authority to an administrative body, to wit: The Food and Drug Administration of the Federal Security Agency of the United States.

HOWLETT and ELSON,

By /s/ EUGENE M. ELSON,
Attorneys for Defendants.

Duly verified.

[Endorsed]: Filed November 10, 1949. [248]

[Title of District Court and Cause No. 10391-PH]

STIPULATION

It Is Hereby Stipulated between counsel for the respective parties, as follows:

I.

That there is on file with the Clerk of the above-entitled Court in United States of America vs. El-O-Pathic Pharmacy, et al., Civil Action No. 10266-PH, among other things, "Points and Authorities in Opposition to Order to Show Cause re Preliminary Injunction"; "Supplemental Points and Authorities in Opposition to Order to Show Cause re Preliminary Injunction"; "Supplemental Affidavit of Martin A. Clemens" (having to do with the allegation in the Complaint for Injunction that 5-milligrams per day of methyl testosterone do not have any therapeutic value); "Supplemental [250] Affidavit of Martin A. Clemens," dated October 21, 1949 (attaching labeling used in connection with certain patent medicines described therein); and "Affidavit of Eugene M. Elson." That the aforesaid documents were filed by the defendants in said action in opposition to the order to show cause issued therein why preliminary injunction should not issue as prayed for.

II.

That the aforesaid affidavits, and each of them, alleged matters and things which are claimed by the defendants to be pertinent to the response of the

defendants in the above-entitled action to the order to show cause issued therein why a preliminary injunction should not issue, and that said affidavits, and each of them, so filed in said action, entitled United States of America vs. El-O-Pathic Pharmacy, a corporation, et al., Civil Action No. 10266-PH, may be considered by the Court and counsel with the same force and effect as though the same had been filed herein by the defendants herein in opposition to the order to show cause issued herein.

III.

That said "Points and Authorities in Opposition to Order to Show Cause re Preliminary Injunction"; and "Supplemental Points and Authorities in Opposition to Order to Show Cause re Preliminary Injunction" so filed in said action entitled United States of America vs. El-O-Pathic Pharmacy, et al., No. 10266-PH, may be considered by the Court and counsel with the same force and effect as though the same had been filed herein in response to the order to show cause why preliminary injunction should not issue herein, provided, however, that counsel for defendants herein may file on behalf of the defendants in this action points and authorities in opposition to said order to show cause, indicating any additional points and authorities applicable to this action alone, and indicating therein any portion of the aforesaid points and authorities and supple-

mental points and authorities which are not [251] applicable to this action.

Dated: November 10, 1949.

HOWLETT and ELSON,

/s/ EUGENE M. ELSON,
Attorneys for Defendants.

JAMES M. CARTER,
United States Attorney,

CLYDE C. DOWNING,
Assistant United States Attorney, Chief Civil Division,

/s/ TOBIAS G. KLINGER,
Assistant United States Attorney, Attorneys for United States of America.

It Is So Ordered this 10th day of November, 1949.

/s/ HARRY C. WESTOVER,
United States District Judge.

Receipt of Copy acknowledged.

[Endorsed]: Filed November 10, 1949. [252]

In the United States District Court for the Southern District of California, Central Division

Civil No. 10391-HW

UNITED STATES OF AMERICA,

Plaintiff,

vs.

HUDSON PRODUCTS COMPANY, a Corporation, and its Subsidiary Firm Doing Business Under the Fictitious Name and Style, MAYWOOD PHARMACAL COMPANY, and ALLEN H. PARKINSON, an Individual,

Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW ON PRAYER FOR PRELIMINARY INJUNCTION

This Court, having considered the pleadings, affidavits, briefs, and oral arguments relating to the plaintiff's prayer for a Preliminary Injunction in this cause, and having denied said prayer on January 11, 1950, now makes the following Findings of Fact and Conclusions of Law, but expressly refrains from making any determination with respect to the ultimate issues of fact and law:

Findings of Fact

(1) If the defendants are violating the Federal Food, Drug, and Cosmetic Act, the public interest can be substantially protected by an early trial on the plaintiff's prayer for a Permanent Injunction.

(2) This case was set for trial in this Court on January 24, 1950, [254] on the plaintiff's prayer for a Permanent Injunction, and on stipulation of the parties the trial date was continued until January 31, 1950.

Conclusions of Law

(1) Where the United States seeks a Preliminary Injunction to prevent alleged violations of the Federal Food, Drug, and Cosmetic Act, and it appears that an early trial can be had on the prayer for a Permanent Injunction which will substantially protect the public interest involved, a Preliminary Injunction should not issue.

(2) The plaintiff's prayer for a Preliminary Injunction is denied.

Dated: Jan. 30th, 1950.

/s/ HARRY C. WESTOVER,
United States District Judge.

Judgment entered Jan. 30, 1950.

Receipt of Copy acknowledged.

[Endorsed]: Filed January 30, 1950. [255]

[Title of District Court and Cause No. 10391-HW Civil.]

STIPULATION AS TO RECORD

In order that this case may be disposed of as quickly as possible,

It Is Stipulated by the parties hereto, through their respective counsel, that the complete record of this case shall consist of the following documents,

all of which are filed in Civil No. 10391-HW, unless otherwise stated:

(1) The Complaint for Injunction filed by the plaintiff;

(2) The supporting affidavits filed by the plaintiff together with their exhibits—namely, the affidavits of Mr. Robert S. Roe, Dr. Clinton Hobart Thienes, Dr. Elmer Belt, and Dr. Ian Macdonald;

(3) Judge McCormick's Order To Show Cause, dated September 29, 1949;

(4) Stipulation, Consent, and Order, signed by Judge Peirson M. Hall, dated October 20, 1949, continuing hearing on Order to Show Cause;

(5) Answer and Amendment to the answer filed by the defendants; [256]

(6) Stipulation Permitting Filing of Amendment to Answer, dated November 10, 1949;

(7) The two Supplemental Affidavits of Martin A. Clemens filed in Civil No. 10266-HW;

(8) Affidavit of Eugene M. Elson filed in Civil No. 10266-HW;

(9) Stipulation dated November 10, 1949, that certain affidavits and briefs filed in Civil No. 10266 may be considered by the Court in the instant case;

(10) Affidavit of Allen H. Parkinson;

(11) Findings of Fact and Conclusions of Law of Judge Westover denying plaintiff's prayer for a Preliminary Injunction;

(12) Supplemental affidavit of Robert S. Roe filed in Civil No. 10266, subject to any objections as to relevancy and materiality;

(13) Affidavit of Walter F. McRae filed in Civil No. 10266, except paragraph (3) thereof and except Exhibit A attached to said affidavit, subject to any objections as to relevancy and materiality;

(14) The Information filed by the Government in United States v. Allen H. Parkinson, No. 20642-Criminal (S.D. Calif.);

(15) The complete transcript of proceedings, including exhibits in the case of United States v. El-O-Pathic Pharmacy et al., No. 20596-Criminal, (S.D. Calif.), which was tried together with the case described in paragraph (14) of this Stipulation, shall be considered part of the record of this case subject to any objections as to its relevancy and materiality; provided, that it is expressly understood (a) that none of the evidence in said transcript pertaining to the danger of using testosterone under certain circumstances was introduced as against said Parkinson, defendant in No. 20642-Criminal, and (b) that there was no charge made by the Government in No. 20642-Criminal that the warning statement on the labeling which related to the testosterone products there involved was not adequate;

(16) Stipulation and Order filed January 17, 1950, continuing the trial in this cause for one week; [257]

(17) If Mr. Hazen Parkinson were called to testify in this proceeding, he would testify, if permitted, in accordance with the offer of proof set forth on pages 762-767 of the transcript of record described in paragraph (15) of this Stipulation.

ERNEST A. TOLIN,
United States Attorney,

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief of Civil Division,

/s/ TOBIAS G. KLINGER,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

HOWLETT and ELSON,
By /s/ EUGENE M. ELSON,
Attorney for Defendants.

[Endorsed]: Filed January 31, 1950. [258]

[Title of District Court and Cause No. 10391-HW.]

STIPULATION AS TO RECORD

It is hereby stipulated between counsel for the respective parties in the above-entitled action as follows:

1. The answer of Hudson Products Company, a corporation; Hudson Products Company, a corporation doing business as Maywood Pharmacal Company; and Allen H. Parkinson, an individual, here-

tofore filed in the above-entitled action, in paragraph IV thereof, inadvertently described Exhibit "C" attached to said Answer and constituting page 10 of said Answer as the carton label used by Hudson Products Company, a corporation, prior to August 26, 1949. Said designation was in error and in fact said carton label designated Exhibit "C" as aforesaid is the carton label used by Hudson Products Company, a corporation, doing [262] business as Maywood Pharmacal Company since August 26, 1949.

2. Said paragraph IV of said Answer incorrectly referred to Exhibit "D" thereto and constituting page 11 of said Answer as the bottle label used by Hudson Products Company, a corporation, prior to August 26, 1949. Said designation was in error and in fact said bottle label Exhibit "D" was used by said Hudson Products Company, a corporation, since August 26, 1949.

3. Said paragraph IV of said Answer incorrectly referred to Exhibit "E" to said Answer, and constituting page 12 of said Answer, as the carton label used by said Hudson Products Company, a corporation, doing business under the fictitious firm name of Maywood Pharmacal Company, since August 26, 1949. Said carton label was in fact used by Hudson Products Company, a corporation, as such, and not

doing business under the fictitious firm name of Maywood Pharmacal Company prior to August 26, 1949.

Dated this 14th day of April, 1950.

ERNEST A. TOLIN,
United States Attorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief of Civil Division.

/s/ GEORGE E. DANIELSON,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

/s/ EUGENE M. ELSON,
Attorney for Defendants.

[Endorsed]: Filed April 14, 1950. [263]

[Title of District Court and Cause No. 10391-HW]

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff having filed a Complaint praying for a preliminary injunction and for a permanent injunction; and the defendants having appeared and answered; and the Court having denied the prayer for a preliminary injunction; and the cause having come on for trial on the plaintiff's prayer for a permanent injunction; and this cause having been consolidated for trial with U. S. v. El-O-Pathic Pharmacy, et al., No. 10-266-HW Civil; and the

parties having offered documentary evidence by stipulation; the Court now makes the following Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure:

Findings of Fact

(1) Defendant Hudson Products Company is a corporation having its principal place of business at 1067 East Anaheim Street, Long Beach, California. [264]

(2) Said Hudson Products Company also trades under the fictitious name and style of Maywood Pharmacal Company at 6812 Hollywood Boulevard, Hollywood, California. All mail orders received by the defendant Maywood Pharmacal Company are filled and mailed by the defendant Hudson Products Company.

(3) Defendant Allen H. Parkinson resides in the County of Los Angeles, California, within the jurisdiction of this Court. He is the president of said Hudson Products Company and is primarily responsible for its policies and activities.

(4) Defendant Parkinson trading as Hudson Products Company was convicted in this Court on July 13, 1949, in Docket No. 20642-Criminal, of violating the Federal Food, Drug, and Cosmetic Act by reason of their distribution of misbranded male and female hormone drugs.

(5) There is no evidence that said defendants

have continued the distribution of female hormone drugs since July 13, 1949.

(6) Subsequent to July 13, 1949, said defendants have changed the labeling of the male hormone drugs which they distribute. They will probably continue the interstate distribution of said drugs as presently labeled on a large scale unless restrained from so doing by this Court.

(7) The male hormone drugs which defendants ship interstate on mail order consist of:

(a) Methyl Testosterone linguets (5 milligrams)

(b) Methyl testosterone combined with a small amount of Vitamin B1 in linguet form (5 milligrams)

These drugs are sold in quantities ranging from 30 tablets to 180 tablets per package.

(8) Said defendants do not require a physician's prescription in their sale of said drugs.

(9) The labels which defendants use on said drugs are those which are set forth in paragraphs 6 and 7 of the Complaint, and which also comprise Exhibits C and D of the Answer filed by the defendants.

(10) The labeling of each of the male hormone drugs which said defendants distribute uses the word "physician" four times in such phrases as "under supervision of a physician." Said labeling includes a statement that a physician should be consulted before taking testosterone.

(11) The labeling of each of said drugs contains adequate directions for use.

(12) The labeling of each of said drugs contains adequate warnings.

(13) The plaintiff has not sustained its burden of proof with respect to its allegations in issue.

(14) The plaintiff has not established that a 5 milligram linguet of methyl testosterone taken once daily is ineffective in the treatment of male hormone deficiency.

Conclusions of Law

(1) This Court has jurisdiction over the subject matter of this cause and the parties thereto.

(2) The male hormone drugs distributed by defendants Allen H. Parkinson and Hudson Products Company are not misbranded within the meaning of 21 U.S.C. 352(f) (1) since the suggestion in the labeling of said drugs that they be taken in consultation with a physician constitutes adequate directions for use.

(3) The male hormone drugs distributed by said defendants are not misbranded within the meaning of 21 U.S.C. 352(f) (2) since the suggestion in the labeling of said drugs that they be taken in consultation with a physician constitutes adequate warnings against use in those pathological conditions where their use may be dangerous to health.

(4) The male hormone drugs distributed by said defendants are not misbranded within the meaning

of 21 U.S.C. 352(a) since it has not been established that the daily intake of methyl testosterone in linguet form is ineffective in the treatment of male hormone deficiency.

(5) The plaintiff's prayer for a permanent injunction is denied.

Dated: May 22nd, 1950.

/s/ HARRY C. WESTOVER,
United States District Judge.

Affidavit of service by mail attached.

[Endorsed]: Filed May 22, 1950. [266]

In the United States District Court in and for the Southern District of California, Central Division

No. 10,391-HW Civil

UNITED STATES OF AMERICA,
Plaintiff,

vs.

HUDSON PRODUCTS COMPANY, et al.,
Defendants.

JUDGMENT

Plaintiff having filed a Complaint praying for a preliminary injunction and for a permanent injunction; and the defendants having appeared and

answered; and the Court having denied the prayer for a preliminary injunction; and the cause having come on for trial on the plaintiff's prayer for a permanent injunction; and this cause having been consolidated for trial with United States v. El-O-Pathic Pharmacy, et al., No. 10,266-HW Civil; and the parties having offered documentary evidence by stipulation; the Court having filed Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure;

It is Therefore Ordered, Adjudged, and Decreed that the plaintiff's prayer for a permanent injunction be, and is hereby denied, and that the Complaint for Injunction be, and is hereby, dismissed.

Dated: May 22nd, 1950.

/s/ HARRY C. WESTOVER,
U. S. District Court Judge.

Judgment entered May 22nd, 1950.

[Endorsed]: Filed May 22, 1950. [268]

[Title of District Court and Cause No. 10266-HW]

and

[Title of District Court and Cause No. 10391-HW]

NOTICE OF APPEAL

Notice Is Hereby Given that the United States of America, plaintiff above named, hereby appeals

to the United States Court of Appeals for the Ninth Circuit from the final judgment entered in the above actions on May 22, 1950.

Dated: July 17, 1950.

ERNEST A. TOLIN,
United States Attorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief, Civil Division.

/s/ GEORGE E. DANIELSON,
Assistant United States Attorney, Attorneys for United States of America, Plaintiff.

Affidavit of Service by Mail attached.

[Endorsed]: Filed July 19, 1950. [412]

[Title of District Court and Cause No. 10266-HW]

and

[Title of District Court and Cause No. 10391-HW]

STATEMENT OF POINTS ON WHICH APPELLANT INTENDS TO RELY ON THE APPEAL

Appellant hereby states the points upon which it intends to rely on appeal: [415]

(1) The District Court erred in holding that the labeling of appellees' drugs bears adequate direc-

tions for use, within the meaning of 21 U.S.C. 352(f)(1).

(2) The District Court erred in holding that the labeling of appellees' drugs bears adequate warnings, within the meaning of 21 U.S.C. 352(f)(2), against use in those pathological conditions where their use may be dangerous to health.

(3) The District Court erred in holding that appellees' drugs are not dangerous to health, within the meaning of 21 U.S.C. 352(j), when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

(4) The District Court erred in holding that the labeling of appellees' drugs [the 5-milligram methyl testosterone linguets, and the combination methyl testosterone and Vitamin B-1 linguets] is not false or misleading within the meaning of 21 U.S.C. 352(a).

(5) The District Court erred in holding that appellant failed to establish that the daily intake of 5 milligrams of methyl testosterone in linguet form is ineffective in the treatment of male hormone deficiency.

(6) The District Court erred in holding that appellees' drugs are not misbranded within the meaning of 21 U.S.C. 352(a), (f)(1), (f)(2), and (j).

(7) The District Court erred in holding that appellant failed to sustain its burden of proof.

(8) The District Court erred in refusing to issue permanent injunctions as prayed to restrain the appellees from further violations of the Federal Food, Drug, and Cosmetic Act.

Respectfully submitted,

ERNEST A. TOLIN,
United States Aatorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief of Civil Division.

/s/ GEORGE E. DANIELSON,
Assistant U. S. Attorney.

[Endorsed]: Filed July 19, 1950. [416]

[Title of District Court and Cause. No. 20596]

INFORMATION

(21 U.S.C. 331 and 333 and 352—Introduction into interstate commerce of misbranded drugs)

Count I

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(2) and 352(j)]

The United States Attorney charges:

That Martin A. Clemens, an individual, trading and doing business under the firm name M. A. Clemens Pharmacy at Los Angeles, State of California, did, within the Central Division of the

Southern District of California, on or about November 1, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Phoenix, State of Arizona, consigned to John R. Winch, a box containing a number of tablets of a drug;

That displayed upon said box was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone [269] makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets	10.00
Box 60 Tablets	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)

426 So. Spring St. Room 502-503 MAdison 6-4171

Los Angeles 13, Calif.

That accompanying said drug, was certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate [270] growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power

and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health in such manner and form as are necessary for the protection of users, in that each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the

meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and [271] suggested in the labeling, to wit, as directed on the box label, "1-2 tablets daily" and as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. [272]

Count II.

[21 U.S.C. 331(a), 333(a), 352(a), 252(f)(2) and 352(j)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned, manager and director of said corporation, did, within the Central Division of the Southern District of California on or about October 30, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate com-

merce at Los Angeles, State of California, for delivery to Phoenix, State of Arizona, consigned to John R. Winch, a box containing a number of tablets of a drug;

That displayed upon said box was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets	10.00
Box 60 Tablets	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to El-O-Pathic Pharmacy 1109½ No. Western Ave. Hollywood 27, Calif.

HOllywood 1722

Note: Please understand this trial size is simply an introductory package and for marked results treatment must be continued over a [273] 30-day period.

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude towards social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many

conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug [274] would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health in such manner and form as are necessary for the protection of users, in that each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was

dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the box label, "1-2 tablets daily" and as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

Count III.

[21 U.S.C. 331(a), 333(a) and 352(a)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned, manager and director of said corporation, did, within the Central Division of the Southern District of California, on or about December 28, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to

Phoenix, State of Arizona, consigned to John R. Winch, a box containing a number of dosules of a drug;

That displayed upon said box was the following labeling:

Menformon Dosules*
Reg. U. S. Pat. Off.
"Roche-Organon"

(Female Sex Hormone Ointment in Individual Dose Containers for Accuracy of Dosage)

Each Dosule contains 1 gram of ointment. The active ingredient of Menformon Dosules is Non-Crystalline Estrone in natural combination with insignificant quantities of Other Naturally Occurring Female Sex Hormones (equilin and equilenin) derived from pregnant mare's urine. The content of estrogenic substances present in each dosule represents the estrus producing activity of 2000 International Units of 0.2 mg. of standard crystalline ketohydroxyestratriene (estrone).

For External Use Only

*The term "Dosules" is a trade mark designating individual dose containers supplied by the owner of the trade mark.

Roche-Organon, Inc. Nutley, New Jersey [276]

For Application:

1. Puncture the tip of the Dosule tube with pin or other pointed instrument.

2. Squeeze out all the ointment spreading it over a wide area for quick absorption.

3. Now rub in briskly for several minutes (usually five or more) until all the ointment is well rubbed in.

Caution: To be dispensed only by or on the prescription of a physician. Prescribed dose should not be exceeded.

Note: A leaflet giving dose schedules and therapeutic indications has been prepared for the convenience of physicians. For safe use, physicians are urged to obtain a copy in the event they are not familiar with the preparation. 24702

Keep in a Cool Place

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would be efficacious to develop the female breasts, to stimulate mammary growth and result in definite breast growth of considerable degree, and that said drug would be efficacious in the treatment of underdeveloped breasts which statements in said circular were false and misleading in that said drug would not be efficacious for such purposes. [277]

Count IV.

[21 U.S.C. 331(k), 333(a), 352(a) and 352(j)]

The United States Attorney further charges:

That Roche-Organon, Inc., trading and doing business at Nutley, State of New Jersey, did, on or about August 6, 1947, ship in interstate commerce from Nutley, State of New Jersey, to Los Angeles, State of California, consigned to the Mote Company, a bottle containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about August 27, 1947, the said Mote Company did sell and deliver to M. A. Clemens Pharmacy at Los Angeles, State of California, said bottle containing said tablets of drug;

That thereafter, to wit, on or about November 18, 1947, and while said tablets of drug contained in said bottle were being held for sale after shipment in interstate commerce at the said M. A. Clemens Pharmacy at Los Angeles, State of California, Martin A. Clemens, an individual, trading and doing business as M. A. Clemens Pharmacy at Los Angeles, State of California, the defendant herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California, cause to be removed a quantity of said drug, namely, 5 tablets, from said bottle and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Robert C. Brandenburg solely

upon the surrender by said Robert C. Brandenburg of money in payment therefor;

That displayed upon said tablets when repacked as aforesaid, was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in [278] applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist) 426 So. Spring St., Room 502-503 MAdison 6-4171

Los Angeles 13, Calif.

That on or about November 18, 1947, and while said tablets of drug were held for sale after shipment in interstate commerce as aforesaid, the said Martin A. Clemens, did at Los Angeles, State of California, cause certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones," to accompany said tablets of drug;

That said act of causing the aforementioned circular to accompany said tablets of drug as afore-

said resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude towards social life and would cause nervousness, exhaustion and melancholy to [279] disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would not correct lack of sexual power and impotence, said drug would not relieve and postpone the many conditions associated with middle age and would not

improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said act of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said act by said defendant of causing said circular to accompany said tablets of drug as afore-

said, was an act done by said defendant while said drug was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of [280] drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [281]

Count V.

[21 U.S.C., 331(k), 333(a), and 352(j)]

The United States Attorney further charges:

That Roche-Organon, Inc., trading and doing business at Nutley, State of New Jersey, did, on or about August 6, 1947, ship in interstate commerce from Nutley, State of New Jersey, to Los Angeles, State of California, consigned to the Mote Company, a bottle containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about August 27, 1947, the said Mote Company did sell and deliver to M. A. Clemens Pharmacy at Los Angeles, State of California, said bottle containing said tablets of drug;

That thereafter, to wit, on or about November 18, 1947, and while said tablets of drug contained in said bottle were being held for sale after shipment in interstate commerce at the said M. A. Clemens Pharmacy at Los Angeles, State of California, Martin A. Clemens, an individual, trading and doing business as M. A. Clemens Pharmacy at Los Angeles, State of California, the defendant herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California,

cause to be removed a quantity of said drug, namely, 5 tablets, from said bottle and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Robert C. Brandenburg solely upon the surrender by said Robert C. Brandenburg of money in payment therefor;

That displayed upon said tablets when repacked as aforesaid, was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in [282] applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503 MAdison 6-4171

Los Angeles 13, Calif.

That said act of causing the removal, repacking and disposal as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was

dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the label, "1-2 tablets daily" would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said act by said defendant of causing the removal from said bottle repacking into said envelope and disposal of said tablets of drug as aforesaid, was an act done by said defendant while said drug was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [283]

Count VI.

[21 U.S.C. 331(k), 333(a), 352(a) and 352(j)]

The United States Attorney further charges:

That Schering Corporation, trading and doing business at Bloomfield, State of New Jersey, did, on or about October 10, 1947, ship in interstate commerce from Bloomfield, State of New Jersey, to Los Angeles, State of California, consigned to Forum

Drug Co., a carton containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about October 16, 1947, the said Forum Drug Co., did sell and deliver to M. A. Clemens Pharmacy at Los Angeles, State of California, said carton containing said tablets of drug;

That thereafter, to wit, on or about October 27, 1947, and while said tablets of drug contained in said carton were being held for sale after shipment in interstate commerce at the said M. A. Clemens Pharmacy at Los Angeles, State of California, Martin A. Clemens, an individual, trading and doing business as M. A. Clemens Pharmacy at Los Angeles, State of California, the defendant herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California, cause to be removed a quantity of said drug, namely, 5 tablets, from said carton and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Allan T. Spiher, Jr., solely upon the surrender by said Allan T. Spiher, Jr., of money in payment therefor;

That displayed upon said tablets when repacked as aforesaid was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The avail-

ability of methyl testosterone [284] makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503 MAdison 6-4171
Los Angeles 13, Calif.

That on or about October 27, 1947, and while said tablets of drug were held for sale after shipment in interstate commerce as aforesaid, the said Martin A. Clemens, did at Los Angeles, State of California, cause certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones," to accompany said tablets of drug;

That said act of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and post-

pone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude towards [285] social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would not correct lack of sexual power and impotence, said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and

would not cause nervousness, exhaustion, and melancholy to disappear;

That said act of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said act by said defendant of causing said circular to accompany said tablets of drug as aforesaid, was an act done by said defendant while said drug was being held for sale after shipment [286] in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [287]

Count VII.

[21 U.S.C. 331 (k), 333(a) and 352 (j)]

The United States Attorney further charges:

That Schering Corporation, trading and doing business at Bloomfield, State of New Jersey, did, on or about October 10, 1947, ship in interstate commerce from Bloomfield, State of New Jersey, to Los Angeles, State of California, consigned to Forum Drug Co., a carton containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about October 16, 1947, the said Forum Drug Co., did sell and deliver to M. A. Clemens Pharmacy at Los Angeles, State of California, said carton containing said tablets of drug;

That thereafter, to wit, on or about October 27, 1947, and while said tablets of drug contained in said carton were being held for sale after shipment in interstate commerce at the said M. A. Clemens Pharmacy at Los Angeles, State of California, Martin A. Clemens, an individual, trading and doing business as M. A. Clemens Pharmacy at Los Angeles, State of California, the defendant herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California, caused to be removed a quantity of said drug, namely, 5 tablets, from said carton and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Allan T. Spiher, Jr., solely upon the

surrender by said Allan T. Spiher, Jr., of money in payment therefore;

That displayed upon said tablets when repacked as aforesaid was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone [288] makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503 MAdison 6-4171
Los Angeles 13, Calif.

That said act of causing the removal, repacking and disposal as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and

suggested in the labeling, to wit, as directed on the label, "1-2 tablets daily" would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said act by said defendant of causing the removal from said bottle repacking into said envelope and disposal of said tablets of drug as aforesaid, was an act done by said defendant while said drug was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [289]

Count VIII.

[21 U.S.C. 331(k), 333(a), 352(a), and 352(j)]

The United States Attorney further charges:

That Ciba Pharmaceutical Products, Inc., trading and doing business at Summit, State of New Jersey, did, on or about November 13, 1947, ship in interstate commerce from Summit, State of New Jersey, to Los Angeles, State of California, consigned to El-O-Pathic Pharmacy, Inc., a bottle containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about November 20, 1947, and while said tablets of drug contained in said bottle were being held for sale after shipment in interstate commerce as aforesaid at the said El-O-Pathic Pharmacy, Inc., at Los Angeles, State of California, the said El-O-Pathic Pharmacy, Inc., a

corporation, organized and existing under the laws of the State of California and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, manager and director of said corporation, the defendants herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California caused to be removed a quantity of said drug, namely, 5 tablets, and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Alan T. Spiher, solely upon the surrender by said Alan T. Spiher of money in payment therefore;

That displayed upon said tablets when repacked as aforesaid was the following label:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone [290] is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to El-O-Pathic Pharmacy
1109½ No. Western Ave. HOllywood 1722

Hollywood 27, Calif.

Note: Please understand this trial size is simply an introductory package and for marked results treatment must be continued over a 30-day period.

That on or about November 20, 1947, and while said tablets of drug were held for sale after shipment in interstate commerce as aforesaid, the said El-O-Pathic Pharmacy, Inc., and Martin A. Clemens, the defendants herein, did at Los Angeles, State of California, cause certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones," to accompany said tablets of drug;

That said acts of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade [291] them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and

would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude towards social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate growth and development of the sex characteristics such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude toward social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said acts of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the fre-

quency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since use of said drug may result in sterility, and such use by [292] individuals with early and incipient caricnoma of the prostate may result in acceleration of the malignant growth;

That said acts by said defendants of causing said circular to accompany said tablets of drug as aforesaid were acts done by said defendants while said drug was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [293]

Count IX.

[21 U.S.C. 331(k), 333(a) and 352(j)]

The United States Attorney further charges:

That Ciba Pharmaceutical Products, Inc., trading and doing business at Summit, State of New Jersey, did, on or about November 13, 1947, ship in interstate commerce from Summit, State of New Jersey, to Los Angeles, State of California, consigned to El-O-Pathic Pharmacy, Inc., a bottle containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about November 20, 1947, and while said tablets of drug contained in said bottle were being held for sale after shipment in interstate commerce as aforesaid at the said El-O-Pathic Pharmacy, Inc., at Los Angeles, State of California, the said El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, manager and director of said corporation, the defendants herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California cause to be removed a quantity of said drug, namely, 5 tablets, and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Alan T. Spiher, solely upon the surrender by said Alan T. Spiher of money in payment therefor;

That displayed upon said tablets when repacked as aforesaid was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. he oral dose of methyl testosterone [294] is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets	10.00
Box 60 Tablets	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to El-O-Pathic Pharmacy
1109½ No. Western Ave. HOllywood 1722
Hollywood 27, Calif.

Note: Please understand this trial size is simply an introductory package and for marked results treatment must be continued over a 30-day period.

That said acts of causing the removal, repacking and disposal as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the label, "1-2 tablets daily" would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said acts by said defendants of causing the removal from said bottle repacking into said envelope and disposal of said tablets of drug as aforesaid, were acts done by said defendants while said drug

was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [295]

Count X.

[21 U.S.C. 331(a), 333(a), 352(b)(2), 352(e)(1), 352(f)(1) and 352(f)(2)]

The United States Attorney further charges:

That Martin A. Clemens, an individual, trading and doing business under the firm name M. A. Clemens Pharmacy at Los Angeles, State of California, did, within the Central Division of the Southern District of California, on or about October 26, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Phoenix, State of Arizona, consigned to Helen Thompson, a box containing a number of tablets of a drug;

That displayed upon said box was the following labeling:

Female

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(b)(2), in that said drug was in package form and it failed to bear a label containing an accurate statement of the quantity of

the contents, to wit, the label of said drug bore no statement of the quantity of the contents;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(e)(1), in that it was a drug not designated solely by a name recognized in an official compendium and its label failed to bear the common or usual name of the drug;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, to wit, the labeling of said drug bore no directions for use; [296]

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health in such manner and form as are necessary for the protection of users in that each tablet of said drug contained 0.5 milligrams of alphaestradiol and the labeling of said drug failed to warn that its unrestricted use may result in injury to the female generative system and that its use by females with early and incipient carcinoma of the breast, cervix and uterus may result in acceleration of the malignant growth. [297]

Count XI.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(2) and 352(j)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned manager and director of said corporation, did, within the Central Division of the Southern District of California on or about December 8, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Phoenix, State of Arizona, consigned to William E. Bryner, a box containing a number of tablets of a drug;

That displayed upon said box was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying an-

drogenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	$ 2.00
Box 30 Tablets	10.00
Box 60 Tablets	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to El-O-Pathic Pharmacy
1109½ No. Western Ave. HOllywood 1722
Hollywood 27, Calif.

Note: Please understand this trial size is simply an introductory package and for marked results, treatment must be continued over a 30-day period.

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness

and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness [299] depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where

its use may be dangerous to health in such manner and form as are necessary for the protection of users, in that each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the box label, "1-2 tablets daily" and as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

Count XII.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1) and 352(f)(2)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation,

organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned manager and director of said corporation, did, within the Central Division of the Southern District of California on or about January 9, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Tucson, State of Arizona, consigned to Joe Smith, a bottle containing a number of linguets of a drug;

That displayed upon said bottle was the following labeling:

75

Metandren Linguets

Trade Mark Reg. U.S. Pat. Off.

Compressed wafers especially designed for absorption from under the tongue or inside the Cheek.

Each linguet contains 5 mg. of Metandren (methyltestosterone), orally active androgen. Caution: To be dispensed only by or on the prescription of a physician.

C
B A

Ciba Pharmaceutical Products, Inc.,

Summit, New Jersey

Literature describing this product is available to physicians upon request.

Made in U.S.A.
2284
1131080

Distributed By El-O-Pathic Company

1109½ No. Western Ave. Los Angeles 27, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action result-

ing in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate [302] growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, to wit, the labeling of said drug bore no directions for use;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce

as aforesaid was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, in that each linguet of said drug contained 5 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its unrestricted use may result in sterility and unrestricted use of said drug by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. [303]

Count XIII.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(2) and 352(j)]

The United States Attorney further charges:

That Martin A. Clemens, an individual, trading and doing business under the firm name M. A. Clemens Pharmacy at Los Angeles, State of California, did, within the Central Division of the Southern District of Calfiornia, on or about January 19, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Tucson, State of Arizona, consigned to D. J. McBride, a bottle containing a number of linguets of a drug;

That displayed upon said bottle was the following labeling:

Male Harmone

Each tablet contains 5 mg. testosterone the form of the true male hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy.

The oral dose of methyl testosterone is 2 tablets daily. Place 2 tablets under the tongue and allow them to dissolve.

Box 50 Tablets Linguets	$ 7.00
Box 100 Tablets Linguets	13.00

Send Mail Orders to

M. A. Clemens (Pharmacist)

426 So. Spring St., Room 502-503,
Los Angeles, 13, Calif.

Successor to Clark's Drugs & Sundries

That accompanying said drug, was certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded [304] within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of

voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, in ability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action re-

sulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and mellancholy to disappear; [305]

That said drug, when caused to be introduced and delivered for introduction into interstate comerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 353(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, in that each linguet of said drug contained 5 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health, when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling since each linguet of said drug contains 5 miligrams of male hormone (methyl testosterone) and the use of a drug containing 5 miligrams of male hormone in each linguet, with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the

bottle label, "2 tablets 3 times daily," would be dangerous to health, since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. [306]

Count XIV.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1), and 352(f)(2)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned manager and director of said corporation, did, within the Central Division of the Southern District of California on or about November 6, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Seattle, State of Washington, consigned to Robert N. Diehl, a bottle containing a number of linguets of a drug;

That displayed upon said bottle was the following labeling:

100 Metandren Linguets
Trade Mark Reg. U.S. Pat. Off.

Compressed wafers especially designed for absorption from under the tongue or inside the cheek.

Each linguet contains 5 mg. of Metandren (methyl testosterone), orally active androgen. Caution: To be dispensed only by or on the prescription of a physician.

C
B A

Ciba Pharmaceutical Products, Inc.
Summit, New Jersey

Literature describing this product is available to physicians upon request.

Made in U.S.A.

2284 111177

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to

concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power [308] and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the

meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, to wit, the labeling of said drug bore no directions for use;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, in that each linguet of said drug contained 5 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its unrestricted use may result in sterility and unrestricted use of said drug by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

/s/ JAMES M. CARTER,
United States Attorney.

By /s/ ARLINE MARTIN,
Assistant U. S. Attorney.

[Endorsed]: Filed March 22, 1949. [309]

[Title of District Court and Cause No. 20642.]

INFORMATION
(21 U.S.C. 331 and 333)
Introduction Into Interstate Commerce
of Misbranded Drugs

Count I.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1)]

The United States Attorney charges:

That Allen H. Parkinson, an individual, trading and doing business under the firm name of Hudson Products Company, at Long Beach, State of California, did, within the Central Division of the Southern District of California, on or about February 27, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Long Beach, State of California, for delivery to Altoona, Commonwealth of Pennsylvania, consigned to Roy H. Downing, a carton containing a number of tablets of a drug;

That displayed upon said carton was the following labeling:

Male Sex Hormones

(30) 10 Mg. Methyl-Testosterone Tablets
Dosage: 1 Tablet Daily

Important—In case of pronounced male sex hormone deficiency take 3 tablets daily [367] for 10 days. After the 10 day period take 1 tablet daily.

Caution: Take Only as Directed

Hudson Products Co. 341 Harding Street
Long Beach 5, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a leaflet entitled "The Male Hormone";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflet entitled "The Male Hormone" contained statements which represented and suggested that said drug was the true male sex hormone and that said drug in the average man in his late forties would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug would be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear, which said statements were false and misleading in that said drug was not the true male sex hormone and said drug in the average man in his late forties, would not stimulate growth

and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated [368] with middle age and would not improve the sense of well being; said drug would not be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, in that the directions for use, to wit, "Dosage: 1 tablet daily Important—In case of pronounced male sex hormone deficiency take 3 tablets daily for ten days. After 10 day period take 1 tablet daily," on the labeling of said drug were not adequate directions for use. [369]

Count II.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1)]

The United States Attorney further charges:

That Allen H. Parkinson, an individual, trading and doing business under the firm name of Hudson Products Company, at Long Beach, State of Californa, did, within the Central Division of the Southern District of California, on or about June 15, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Long Beach, State of California, for delivery to Chicago, State of Illinois, consigned to Charles Dank, a carton containing a number of tablets of a drug;

That displayed upon said carton was the following labeling:

Male Sex Hormones

(30) 10 Mg. Methyl-Testosterone Tablets

Suggested Dosage: 1 Tablet Daily

Important: In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician.

Warning: The male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate.

Not for use by children. Caution—take only as directed.

Hudson Products Co. 341 Harding St.

Long Beach 5, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a leaflet entitled "The Male Hormone";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflet entitled "The Male Hormone" contained statements which represented and suggested that said drug was the true male sex hormone and that said [370] drug in the average man in his late forties would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug would be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear, which said statements were false and misleading in that said drug was not the true male sex hormone and said drug in the average man in his late forties,

would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352 (f)(1), in that the labeling of said drug failed to bear adequate directions for use, in that the [371] directions for use, to wit, "Dosage: 1 tablet daily Important—In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician," on the labeling of said drug were not adequate directions for use. [372]

Count III.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1)]

The United States Attorney further charges:

That Allen H. Parkinson, an individual, trading and doing business under the firm name of Hudson Products Company, at Long Beach, State of California, did, within the Central Division of the Southern District of California, on or about August 3, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Long Beach, State of California, for delivery to Seattle, State of Washington, consigned to Armond W. Welch, a carton containing a number of tablets of a drug;

That displayed upon said carton was the following labeling:

Male Sex Hormones

(30) 10 Mg. Methyl-Testosterone Tablets

Suggested Dosage: 1 Tablet Daily

Important: In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician.

Warning: The male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate.

Not for use by children. Caution—take only as directed.

Hudson Products Co. 341 Harding St.

Long Beach 5, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a leaflet entitled "The Male Hormone" and a leaflet entitled "The Story of Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflet entitled "The Male Hormone" contained statements which represented and [373] suggested that said drug was the true male sex hormone and that said drug in the average man in his late forties would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug would be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear, which said statements were false and misleading in that said drug was not the true male sex hormone and said drug in the average man in his

late forties, would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear; [374]

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflet entitled "The Story of Hormones" contained statements which represented and suggested that in the average man said drug would relieve and postpone the many conditions formerly thought to be inevitable with middle age; that said drug would be efficacious in the treatment of nervous tension and intense subjective nervousness and irritability; that said drug would be efficacious in the treatment of numbness in the extremities and itching, prickling

and tingling of the skin on waking up at night; that said drug would be efficacious in the treatment of headaches; that said drug would prevent a decrease in the ability to concentrate and would remedy faulty memory; that said drug would be efficacious in the treatment of depression and melancholia; that said drug would correct a lack of interest in social and business life, lack of mental concentration, and lack of energy; that said drug would correct a feeling of inadequacy and impotency; that said drug would be efficacious in the treatment of hot flashes and feelings of smothering and sweating and chilly, creepy sensations; that said drug would prevent the user from tiring easily and gaining excessive weight; that said drug would be efficacious in the treatment of constipation, vague digestive complaints, and precordial angina pectoris-like pains; that said drug would be efficacious in the treatment of urinary symptoms, such as frequency, nocturia, dribbling, and inability to start urinary stream; that said drug would restore confidence in mental reactions and decisions, and would notably increase the user's capacity for mental and physical work and that said drug would increase potency and libido; which statements were false and misleading in that said drug in the average man would not relieve and postpone the many conditions formerly thought to be inevitable with middle age; said drug would not be efficacious in the treatment of nervous tension and intense subjective nervousness [375] and irritability, said drug would not be efficacious in the treatment of numbness in the extremities

and itching, prickling and tingling of the skin on waking up at night; said drug would not be efficacious in the treatment of headaches; said drug would not prevent a decrease in the ability to concentrate and would not remedy faulty memory; said drug would not be efficacious in the treatment of depression and melancholia; said drug would not correct a lack of interest in social and business life, lack of mental concentration, and lack of energy, said drug would not correct a feeling of inadequacy and impotency, said drug would not be efficacious in the treatment of hot flashes and feelings of smothering and sweating and chilly, creepy sensations; said drug would not prevent the user from tiring easily and gaining excessive weight; said drug would not be efficacious in the treatment of constipation, vague digestive complaints and precordial angina pectoris-like pains; said drug would not be efficacious in the treatment of urinary symptoms, such as frequency, nocturia, dribbling, and inability to start urinary stream; said drug would not restore confidence in mental reactions and decisions, and would not notably increase the user's capacity for mental and physical work; and said drug would not increase potency, and libido;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, in that the directions for use, to wit, "Dosage: 1 tablet daily. Important: In case of pronounced

male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10-day period take 1 tablet daily before meals or as directed by your physician," on the labeling of said drug, were not adequate directions for use. [376]

Count IV.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1), 352(f)(2), 352(j)]

The United States Attorney further charges:

That Allen H. Parkinson, an individual, trading and doing business under the firm name of Hudson Products Company, at Long Beach, State of California, did, within the Central Division of the Southern District of California, on or about August 3, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Long Beach, State of California, for delivery to Seattle, State of Washington, consigned to Armond M. Welch, a carton containing a number of tablets of a drug;

That displayed upon said carton was the following labeling:

Female Hormones

(30) 0.1 Mg. Cryst. a-Estradiol

Important: In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily or as directed by your physician.

Warning: The female hormone should not be used by women with cancer or pre-cancerous lesions of the breast or genital organs.

Not for use by children. Caution—take only as directed.

Hudson Products Co. 341 Harding St.

Long Beach 5, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a leaflet entitled "The Male Hormone," and a leaflet entitled "The Story of Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflets contained statements which represented and suggested that said drug, in women, would relieve and postpone the conditions associated with middle age; that said drug would bring prompt relief from hot flashes, emotional disturbances and other manifestations associated with the menopause; that said drug would be efficacious to [377] bring about a steady readjustment and to help overcome most menopausal conditions in woman approaching or passing through the menopause, which statements were false and misleading in that said drug would not be efficacious in woman to relieve and postpone the conditions associated with middle age; said drug would not bring prompt relief from hot flashes, emotional disturbances and other manifestations associated with

the menopause; and said drug would not be efficacious to bring about a steady readjustment and to help overcome most menopausal conditions in woman approaching or passing through the menopause;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, to wit, the directions for use, "Just One Tablet A Day" in the aforementioned leaflet and "In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily or as directed by your physician," borne on the carton label, were not adequate directions for use;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users in that each tablet of said drug contained .1 milligram of crystalline alpha estradiol and the labeling of said drug failed to warn that the use of said drug in the dosage and with the duration of administration recommended on its labeling may result in uterine bleeding and damage to the ovaries;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce

as aforesaid, was further misbranded within the meaning of 352(j), in that said drug was dangerous to [378] health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling since each tablet of said drug contained .1 milligram of crystalline alpha estradiol and the use of a drug containing .1 milligram of crystalline alpha estradiol with the frequency prescribed, recommended and suggested in its labeling, to wit, as directed on the box label, "3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily" would be dangerous to health since such use of said drug may result in uterine bleeding and damage to the ovaries.

JAMES M. CARTER,
United States Attorney.

By /s/ ARLINE MARTIN,
Asst. United States Attorney.

[Endorsed]: Filed April 8, 1949. [379]

United States of America in and for the Southern District of California, Central Division

No. 20596—Criminal

UNITED STATES OF AMERICA,
Plaintiff,

vs.

EL-O-PATHIC PHARMACY, INC., a Corporation, and MARTIN A. CLEMENS, an Individual, Manager and Director of Said Corporation, and MARTIN A. CLEMENS, an Individual, Trading as M. A. CLEMENS PHARMACY,
Defendants.

Honorable Delbert E. Metzger, Judge presiding

REPORTERS' TRANSCRIPT OF PROCEEDINGS

Los Angeles, California
June 22, 1949

Appearances:

For the Plaintiff:

JAMES M. CARTER,
United States Attorney; by

GEORGE E. DANIELSON,
Assistant United States Attorney, and

NORMAN W. NEUKOM,
Assistant United States Attorney.

For the Defendants:

CARL B. STURZENACKER, ESQ., and
EUGENE M. ELSON, ESQ.,

1204 Taft Building,
1680 North Vine Street,
Hollywood 28, California. [2*]

The Clerk: No. 20596, United States of America vs. El-O-Pathic Pharmacy, Inc., and Martin A. Clemens.

Mr. Danielson: Ready for the government.
Mr. Elson: Ready for the defendants.
The Clerk: Your name is——
Mr. Danielson: George E. Danielson.
The Clerk: Thank you. And your name, sir?
Mr. Elson: Eugene M. Elson.
The Clerk: And is the defendant Martin A. Clemens present?
Martin A. Clemens: Yes.
Mr. Elson: He is. [3]

* * *

(Counsel for the Government and the Defendants then filed a Stipulation as to Facts.)

* * *

Mr. Danielson: Dr. Thienes, please.

CLINTON H. THIENES, M.D.

called as a witness on behalf of the government, being first duly sworn, testified as follows: [10]

*** Page numbering appearing at top of page of original Reporter's Transcript of Record.**

(Testimony of Clinton H. Thienes, M.D.)

Direct Examination

* * *

(Government's Exhibits 1-15 were then admitted in evidence without objection.)

* * *

Q. (By Mr. Danielson): Doctor, will you state your address, please?

A. I live in Los Angeles.

Q. And what is your present occupation?

A. I am Professor of Pharmacology and Toxicology and Head of the Department of Pharmacology and Toxicology in the University of Southern California.

Q. Of what school or schools are you a graduate and with what degrees and the dates, please?

A. I received the Bachelor of Arts Degree from the University of Oregon in 1918. In 1923, I received the Doctor of Medicine Degree and the Master of Arts Degree from the [12] University of Oregon, having completed a course in medicine at the University Medical School.

Mr. Elson: Will you speak a little louder, Doctor?

The Witness: Yes.

And, having done work there, I received the Graduate Degree of Master of Arts during that period, five years.

Q. (By Mr. Danielson): Have you had any post-graduate work, Doctor, other than that described?

A. I did post-graduate work also at Stanford

(Testimony of Clinton H. Thienes, M.D.)

University Medical School. I received the Doctor of Philosophy Degree in 1926 from Stanford University.

Q. And what was your major subject or specialty in getting that degree?

A. Pharmacology and toxicology.

Q. Are you a member of any scientific medical body?

A. Yes; I am a member of the American Society of Pharmacology and Experimental Therapeutics, Incorporated, the International Society known as the Society for Experimental Biology and Medicine, the American Association for Advancement of Science, and a Fellow of the American Medical Association. I am a member of the Los Angeles County Medical Association and the California Medical Association, the Western Society for Clinical Research, and I am an honorary member of the Los Angeles Society of Internal Medicine and the Los Angeles Academy of Medicine. I am a member of the Western [13] Society for Psychosomatic Medicine.

Q. Doctor, are you recognized in any biographical encyclopedia, such as Who's Who?

A. Yes.

Q. What would some of those be, please?

A. I am in Who's Who in America, American Men of Science, Leaders in Education, and a number of other Who's Who, one of them an international Who's Who.

Q. Have you published any books, Doctor?

(Testimony of Clinton H. Thienes, M.D.)

A. I have published a textbook of toxicology, called the Clinical Toxicology, and a textbook of pharmacology, known as Fundamentals of Pharmacology, and a field manual in toxicology for agricultural workers.

Q. Do you know whether any of these books are used in colleges or universities?

A. The first two are used in quite a number of the universities of this country and abroad.

Q. Have you published any other scientific papers, articles or other literature?

A. There is a list of 115 scientific periodicals of which I am either the author or the director of the research and the writing of the paper.

Q. And what subject were you principally interested in in these writings?

A. Pharmacology and toxicology. [14]

Q. Have you in the past, Doctor, engaged in the practice of medicine? A. I have.

Q. For about how long?

A. I have been licensed to practice medicine since 1928 and have practiced as a consultant since then.

Q. You are still practicing as a consultant?

A. I am. And I have had a private office, for private patients, six or seven years. [15]

Q. (By Mr. Danielson): You are a specialist in what field, Doctor, if any?

A. In practice or as a scientist?

Q. As a scientist.

A. Pharmacological and toxicological.

(Testimony of Clinton H. Thienes, M.D.)

Q. What is pharmacology, Doctor?

A. Pharmacology is the science of the nature and action of drugs or medicines.

The Court: I do not recall whether you stated that you are a member of the A.M.A.?

The Witness: I am a fellow of the American Medical Association.

The Court: Have you any connection with naturopathic organizations?

The Witness: No, sir.

Q. (By Mr. Danielson): Does pharmacology include any study of the effects of these drugs that you mention?

A. Which drugs are you referring to, sir?

Q. You have mentioned that pharmacology is a study of the science of drugs and toxic effects.

A. And nature and actions to the uses, I should have said, therapeutic uses.

Q. Would that be as to humans as well as animals? A. Yes, certainly.

Q. Well, does it include a study of the toxic or dangerous [16] effects as well as these drugs?

A. It does.

Q. Are you familiar with the male sex hormones, Doctor? A. Yes.

Q. Is one of these hormones commonly designated as testosterone? A. It is.

Q. Do you know whether the body of the normal male adult generates testosterone?

A. Yes, it does.

(Testimony of Clinton H. Thienes, M.D.)

Q. In what form? A. As testosterone.

Q. Just pure testosterone, is that correct?

A. Yes.

Q. And that is generated by what organ or organs? A. The testes.

Q. Is that a gland, Doctor?

A. Yes, it is a gland.

Q. Does the body of the male adult always provide an adequate supply of testosterone?

A. No.

Q. In such event of a deficiency, can it be supplied to an individual? A. Yes, it can be. [17]

Q. Now, in what form, Doctor?

A. Well, as testosterone or as testosterone propionate or acetate or as methyl testosterone. These are the principal forms in which it is used.

Q. Doctor, would you speak a little louder, please, and would you explain how these forms are actually different from pure testosterone, particularly methyl testosterone?

A. The difference between testosterone and methyl testosterone is that there is an extra atom of carbon and three extra atoms of hydrogen in the molecule, the one atom of carbon and three of hydrogen being joined together in the form of the methyl radical, CH3 radical, which is attached to one of the carbon atoms of the testosterone.

Q. What is the practical effect of that difference from pure testosterone?

A. The methyl radical makes the compound more readily absorbed from the digestive tract.

(Testimony of Clinton H. Thienes, M.D.)

Q. Now, again, in the event of a deficiency of testosterone in the males, can this deficiency be supplied to a human?

A. You mean the method of administration?

Q. That is correct, the routing I mean.

A. Methyl testosterone may be supplied in tablets, to be swallowed, or in small tablets often known as linguets to be placed under the tongue and allowed to slowly dissolve and [18] be absorbed by the mucuous membrane under the tongue.

Testosterone must be injected, although it is given by mouth, but its absorption from the digestive tract is poor. So that usually it is injected, either in solution, in an oil, or as crystals suspended in water or saline or glucose, or as pellets which are implanted under the skin or into a muscle surgically.

Testosterone dipropionate is usually dissolved in an oil and injected.

Q. Doctor, what, if any, difference is there in the effect of administering testosterone in these different forms or by different routes?

A. No difference. They all have the same effect.

Q. And what is that effect, that is, the effect of what? A. The effect of testosterone.

Q. Are you familiar, Doctor, with the female sex hormones? A. Yes.

Q. What are they called, generically?

A. There are two classifications. One class are the estrogens and the other might be called the progestational hormone.

Q. What is the meaning the the term estrogens?

(Testimony of Clinton H. Thienes, M.D.)

A. They are the hormones which are compounds which [19] cause estrus (e-s-t-r-u-s) and there are other spellings as well, in animals and in human and produce analogous effects such as increase in the size and number of cells in the uterus and mammary gland.

Q. Does the body of the normal female adult human generate estrogens? A. It does.

Q. In what form?

A. Principally estradiol or alpha estradiol.

Q. And what gland or glands generate this?

A. The ovary, principally.

Q. Does the body of the normal female human adult always generate an adequate supply?

A. No, it does not.

Q. Can these estrogens be supplied to a woman who is deficient in her own natural supply?

A. It can.

Q. In what ways can it be supplied?

A. Either in oral solution, the alpha estradiol or estrone or similar compounds, which are products of metabolism of the estradiol and have the same type of effect; they may be dissolved in oil and injected; they may be combined with certain radicals such as the benzoate estradiol, propionate or dipropionate and dissolved in oil and injected, or they may be given by mouth; and certain radicals attached to [20] estradiol will make it more easily absorbed, just as in the case of testosterone, and then the crystals may be suspended in water and

(Testimony of Clinton H. Thienes, M.D.)

injected or made into pellets and surgically implanted under the skin or into the muscle.

The Court: What is propionate?

The Witness: Propionate, that is an acid radical, an organic acid containing three carbon atoms, which combines—which can be made to combine with estradiol, alpha estradiol, to form a more complex compound which is more slowly disintegrated in the body and therefore acts longer than the alpha estradiol.

The Court: Is that the purpose of the combination?

The Witness: In the case of alpha estradiol dipropionate it is to give a more prolonged action.

The Court: Can the estrogens be supplied by rubbing on the skin, Doctor?

A. Yes, they may be dissolved in fatty materials or in fat solvents and applied to the skin.

Q. Does the normal female human adult continue to have a source of natural supply, a natural source of supply of estrogens throughout her life?

A. At the period we call the menopause or the change of life, the secretion of the natural estrogens is reduced to a very small amount and may be entirely stopped.

Q. Now, you have described the various, different forms [21] of estrogens in the female hormone and the various, different manners of administration. Is there any difference in the effect by administering it in these different manners or in the different forms? A. No.

(Testimony of Clinton H. Thienes, M.D.)

The Court: Is there, as to the efficiency?

A. Well, that is a matter of dosage and efficiency of absorption, of course. For instance, when rubbed on the skin, the amount that gets into circulation for a given weight of the compound applied would be usually less than that which would get into circulation from injection.

Q. (By Mr. Danielson): Now, Doctor, you testified that the generic term for one class of the female sex hormone is estrogens. Are there other estrogens besides alpha estradiol?

A. Yes, there is estrone, which is secreted into the urine of humans and many animals, also known as theelin, which is widely used. It is less potent but, by giving a large dose, the same results are obtained as with estradiol, and then there is a similar compound excreted into the urine and known as estriol or theelol. Then, there are others, still, especially which are found in the urine of horses, known as equilin and equilenin. These are of minor importance, medically.

Q. Are all these natural estrogens, Doctor? [22]

A. Yes. All that I have named are natural estrogens.

Q. Are the effects of all natural estrogens the same?

A. As far as the effect upon the uterus and the breasts and the skin, yes.

Q. Now, Doctor, in your profession as pharmacologist, are you familiar with the United States

(Testimony of Clinton H. Thienes, M.D.)

Pharmacopoeia, Official National Formulary and the Official Homeopathic Pharmacopoeia of the United States? A. I am.

Q. Have you examined these publications to ascertain whether they mention the drug alpha estradiol?

A. The United States Pharmacopoeia lists it.

Q. And by what name is this drug designated in the United States Pharmacopoeia?

A. As estradiol and as alpha estradiol.

Q. Is this drug also designated in the United States Pharmacopoeia by the name Female?

A. No.

Q. Have you examined the three compendia which I have named to determine whether there is any drug listed under the name Female?

A. I have, and I have found no such drug.

Q. What is the common or usual name of alpha estradiol?

A. It is either alpha estradiol or estradiol.

Q. Is it ever referred to commonly or usually as female? [23] A. No.

Q. Now, Doctor, on the basis of your education, your professional training and experience, your study of the scientific literature, medical literature, your participation in conferences and discussions with other doctors and other scientists and your research and clinical experience, do you know the concensus of medical opinion regarding the toxic effects which methyl testosterone may have upon the adult male? [24] A. Yes, I think I do.

(Testimony of Clinton H. Thienes, M.D.)

Q. What is that consensus of medical opinion?

Mr. Elson: I object to that, on the ground that it calls for a conclusion of the witness and there is no foundation laid. It may be true that the doctor has had considerable experience in reading and in conferences and so on, but we still don't know what the consensus of medical opinion is and how far-reaching it is necessary to go in order to determine it. It might be the consensus of opinion in this locality, but, what would be a consensus of opinion here would not necessarily be the consensus of opinion nationally or internationally or in some other locality.

Mr. Danielson: If your Honor please, the defendants' objection I believe is as to the weight or credibility of this doctor, of this witness' opinion, rather than as to whether or not it should be admissible. Similar points have been raised before, and there is precedent within the Ninth Circuit as to the admissibility of a qualified witness' opinion as to the consensus of medical opinion. In the case of Research Laboratories vs. The United States, decided in April, 1948, by the Ninth Circuit Court, reported in 167 F(2d) 410——

The Court: Yes. Well, upon the doctor's qualifications, I think that his opinion on that subject should be admitted, subject, of course, to cross-examination as to how far it may reach or what its limits may be. I overrule the objection. [25]

* * *

(Testimony of Clinton H. Thienes, M.D.)

A. The methyl testosterone may produce a condition which is known as aligospermic, or even aspermia. These conditions are characterized by deficiency or absence of spermatozoa formation or liberation, and also it has been known to exaggerate or hasten the development of carcinoma, cancer of the prostate gland in males.

Q. Doctor, what do you mean by aligospermia, please?

A. Deficiency in the number of sperm or spermatozoa which are liberated by the male.

Q. What does that mean, in ordinary language?

A. Well, it would mean a deficiency in the ability to reproduce.

Q. And what is the meaning of aspermia, Doctor? A. Absence of sperm.

Q. Now, you have stated what is the consensus of medical opinion. Is that your own opinion, also based upon the same background? A. Yes.

Q. Would you explain what you mean by carcinoma of the prostate, how would you define that?

A. Well, another term is cancer of the prostate. The [26] prostate gland is a gland in the male which is one of the secondary reproductive glands. It secretes a fluid for carrying the sperm and it contains epithelial cells which are the secretary cells. Now, some of these epithelial cells, new cells of the type we call malignant or cancerous may develop; and in the early carcinoma or early cancer, the presence of the cancerous growth may not be recognized. It often occurs in middle age, at about the

(Testimony of Clinton H. Thienes, M.D.)

time that the sex hormone may decrease in the amount of production and testosterone might be given to relieve the symptoms which the individual feels as a result of deficient secretion of testosterone and the administration, then, of the methyl testosterone would stimulate the cancerous growth and perhaps carry it to the point where it is no longer curable.

Mr. Elson: I did not hear the last.

The Witness: Well, the cancerous growth might develop under the influence of methyl testosterone to the point where it is no longer curable.

Q. (By The Court): Now, normally, the human system, through what, the glands, supplies some testosterone? A. Yes.

Q. And that may diminish with physical conditions or age?

A. Yes, or infections, or a number of other things.

Q. And to attempt to supply that, you say creates a [27] danger?

A. Yes, there is a danger, and if the patient is not being carefully observed, the cancer would develop beyond the point of curability. In other words, a physician supplying testosterone or methyl testosterone, or any of its forms, is aware of this danger and therefore he examines the patient at frequent intervals, to see that there is no tumor developing in the prostate gland.

Q. (By The Court): Well, is there any condition you know of where the system may create an

(Testimony of Clinton H. Thienes, M.D.)

oversupply of that, without being aided by testosterone?

A. By the administration of it, you mean?

Q. Yes. The reason the thought occurs to me is that it is generally known that there are many cases of cancer of the prostate gland? A. Yes.

Q. (By The Court): And I was just wondering why that gland seems to be quite susceptible to a cancerous growth.

A. I don't think that we can answer that question, sir. We don't know yet why a given gland is more susceptible to a given type of cancer. We just know of this relationship. We know that in cancer of the prostate, that castration will aid in the cure or at least diminish the rate of development of the cancer of the prostate and of course castration removes the source of the secretion of natural testosterone. [28]

Q. (By The Court): Would the diminution in the supply of testosterone have any effect toward promoting a cancerous condition?

A. Not in the prostate.

Q. (By The Court): It would not?

A. It would inhibit the development of the cancer in the prostate, when the testosterone secretion is diminished.

Q. (By The Court): Would changes of habits in life or dietary or other conditions of that sort tend to enlarge or increase the amount supplied by the human system?

A. Well, a defective diet, starvation or malnutri-

(Testimony of Clinton H. Thienes, M.D.)

tion will decrease the function of the testes and therefore would decrease the secretion. That is the only situation in which I think diet would influence it. A defective diet will definitely decrease the activity in the size of the testes. As far as other conditions in life are concerned, I don't think we have enough information to answer that question.

The Court: All right. Well, I trust that neither you, Doctor, or counsel consider the court as cross-examining the witness.

Mr. Neukom: No, no.

The Court: These thoughts occurred to me. I would like to have a little more expansion and it is for the betterment of my understanding that I am asking these questions as we go along. Proceed. [29]

Q. (By Mr. Danielson): In view of what you have just testified, Doctor, would the acceleration of a prostatic cancer be dangerous? A. Oh, yes.

Q. And why? What are your reasons for that?

A. Rapidly growing cancers will tend to disseminate through the lymphatic channels of the body to other parts of the body. A cancer is a serious thing, because cells or portions of the tumor break off into the lympth and blood channels and are carried to other parts of the body where they develop and often cannot be reached surgically. If a cancerous growth was limited to the point of origin, that is, if a prostatic cancer in this case remained in the area of the prostate, it could be removed surgically. But the danger of cancer is, and especially of the rapidly developing ones, that

(Testimony of Clinton H. Thienes, M.D.)

cancerous cells break off from the original growth and migrate into other parts of the body, particularly through channels, particularly the lympth channels, and locate in bones and the brain and various parts of the body where often they cannot be removed.

Q. Doctor, a while back, when I was asking you questions relative to the various compendia, the pharmacopeia, I see that I failed to ask you whether alpha estradiol was designated in either of the National Formulary or the Homeopathic Pharmacopoeia of the United States. [30]

A. No. They are not in either of those.

Mr. Danielson: Counsel, will you stipulate that those three are the three——

Counsel will stipulate, your Honor, that the United States Pharmacopoeia, the National Formulary and the official Homeopathic Pharmacopoeia of the United States are the official compendia. That is correct, is it not, Mr. Elson?

Mr. Elson: Yes.

Q. (By Mr. Danielson): Doctor, on the basis of your education, your professional training, experience, your studies of these medical and scientific literature, conferences, discussions with other doctors and scientists and your clinical laboratory experience, do you know the consensus of medical opinion regarding the toxic effects which alpha estradiol may have upon the adult female?

A. Yes.

(Testimony of Clinton H. Thienes, M.D.)

Q. And what is that consensus of medical opinion?

A. In line with the testimony I have just given about the male hormone, it is that it also accelerates cancerous growth, particularly in the female breast, also in the male breast as far as that is concerned; long-continued administration also leads to tumors particularly of the uterus and may interfere with the normal menstrual cycle.

Q. (By Mr. Danielson): It is likewise your opinion based upon the same background? [31]

A. Yes.

Mr. Danielson: You may cross-examine. [32]

* * *

Cross-Examination

By Mr. Elson:

Q. Doctor, we are concerned in this case, so far as carcinoma of the prostate, with its early and incipient stages. That is the language that is employed in the information. Can you diagnose the presence of carcinoma of the prostate in an individual in its incipient stages?

A. As a rule, not.

Q. Isn't it also true that, when you are able to diagnose [33] carcinoma of the prostate in an individual, it is no longer incipient?

A. I suppose that is a matter of definition but, in general, I would say that is true, except for this, if I may say it. In case the prostate is large and

(Testimony of Clinton H. Thienes, M.D.)

is removed, then, of course, the carcinomous process can be identified by the pathologist.

Q. But, until it is removed, it is quite difficult to determine it in every case, isn't it?

A. Yes.

Q. Your methods of diagnosing that condition are by palpation and biopsy, are they not?

A. In general, that is true.

Q. In other words, a biopsy is going in and taking a specimen of the material, is it not?

A. That is right.

Q. And then, in the case where you suspect that there might be a carcinoma of the prostate, you don't remove the prostate but you perform a biopsy and take a specimen of the material, and it might well be that the specimen you take is not part of the affected area, isn't that true?

A. If biopsy is done; yes.

Q. And isn't it also true that there can be a carcinoma of the prostate that will have with it a benign hypertrophy? A. Yes. [34]

Q. Cancer of the prostate in an individual, after it has passed its incipient stage, is usually associated with manifestations that the patient feels in some way, are they not, or is it not?

A. Not necessarily.

Q. What are the manifestations that the ordinary person feels because of a prostatic cancer?

A. Usually difficulty in urination because of the pressure of the enlargement upon the urethra, the urinary tract.

(Testimony of Clinton H. Thienes, M.D.)

Q. Anything else?

A. We are talking about the early form, are we?

Q. No. I am talking about it after it has passed its incipient stage.

A. If it has got to the point where it is metasticized, there would be symptoms from other organs into which the cancerous cells have scattered and begun to grow.

Q. And hasn't it been your experience that a person whose condition is affected by a prostatic cancer that has passed the incipient stage and is diagnosible comes to a doctor for relief, not knowing what it may be, but for relief anyway?

A. Yes.

Q. And the doctor examines him to determine whether he has a prostatic cancer, and, if he finds one, I take it that [35] one of the things he advises him is not to take any testosterone?

A. That is true.

Q. The urologist is usually the one who does this prostatic examination for a cancer, doesn't he?

A. No; I don't know that.

Q. Isn't it usual, if a man goes to his own physician, who is simply an internist, and the doctor suspects that the man may have cancer of the prostate, he sends him to a urologist to make that examination?

A. If he goes to an internist, he is sent to an urologist.

Q. And, if he goes there first to the urologist, he is there anyway? A. That is right.

(Testimony of Clinton H. Thienes, M.D.)

Q. Isn't it your experience and isn't it your opinion that, if a man went to an urologist, and prostatic cancer was advised, the urologist would, of course, so advise his own doctor, and that his own doctor then would advise him not to take any testosterone and would not prescribe it for him, if he otherwise showed symptoms in which it was ordinarily used?

A. You put several things together. I would say "Yes" to some and "No" to others. I think it should be divided up so I can answer each part.

Q. Would you tell us, then, what you mean by "Yes" and what you mean by "No" and as to which parts of my compound question?

Mr. Danielson: Could the question be read back? It is rather confusing.

Mr. Elson: Surely.

The Court: Yes.

(Question read by reporter.)

Q. (By Mr. Elson): Do you understand the question? A. I think so.

Q. If you don't, I don't want you to be confused. I will put it in another way and see if I can straighten it out. Let's take a hypothetical example of a man who goes to see his own doctor and, from the history of the patient, the doctor suspects that probably or possibly he might have a cancer of the prostate. Let's assume that the doctor sends him then to an urologist for such examination and the urologist, after examining him, concludes that he

(Testimony of Clinton H. Thienes, M.D.)

does have a cancer of the prostate and so advises the man's doctor. Let's assume that the man goes then back to his doctor and that he is manifesting symptoms of the climacteric. Isn't it true that his own doctor under those circumstances would not prescribe testosterone for him and would advise against the use of it by him? A. Yes. [37]

Q. If that same man had gone to the urologist and he had an incipient carcinoma of the prostate, which the urologist was unable to discover either by palpation or by biopsy, and the urologist so advised the man's own doctor, and that same man had symptoms of male climacteric, is it your opinion that ordinarily such a doctor would prescribe testosterone propionate for him and maybe later methyl testosterone?

A. In many instances, I think the physician probably would prescribe one of the testosterone preparations. I am assuming, of course, that the symptomatology is adequate for the diagnosis of male climacteric, which is a very unusual diagnosis.

Q. I assumed that in my question also.

* * *

The Witness: Perhaps I should say it is a very unusual correct diagnosis.

Q. (By Mr. Elson): Do you mean that it is unusual for a doctor to correctly diagnose whether a man is going through the male climacteric?

A. What I mean is that male climacteric is a very unusual condition and that this hypothetical

(Testimony of Clinton H. Thienes, M.D.)

situation which you [38] describe would be a very unusual one.

Q. Whether you call it the male climacteric or not, let us take an individual who has flushes, sweats, extremely nervous, inability to concentrate, nocturia. Let's say that he is a man around 50 years old or so. I don't mean to be all inclusive in the symptoms that I have just related. But isn't it your opinion that the average general practitioner, other things being equal, would under those circumstances prescribe testosterone for a period of time and wait and see whether the symptoms were relieved?

* * *

The Witness: I think we would have to know more of what the general practitioner's examination had consisted in and what the report—or what the urologist may have done in the way of examination, to answer that question.

Q. (By Mr. Elson): Let's assume that the urologist's report was that he had palpated the prostate and performed a biopsy and there was no evidence of cancer of the prostate.

A. And no enlargement of the prostate? [39]

Q. No. A. What about laboratory tests?

Q. Of what?

A. Oh, excretion of hormones.

Q. All right. Let's include that, that there was a laboratory test conducted.

A. With what results?

Q. What? A. With what results?

(Testimony of Clinton H. Thienes, M.D.)

Q. Negative.

A. I don't know what you mean by "negative" there.

Q. Well, with nothing to indicate as a result of that laboratory test that there was any presence of cancer of the prostate.

A. But that wouldn't be adequate.

Q. What would be adequate?

A. You would have to have proof that there was a marked decrease in the secretion of testosterone.

Q. Is it your opinion that such a complete examination is made in every case that an individual is sent to an urologist?

A. Well, I would say it would depend on what the urologist was asked but I think also that most competent urologists would insist upon—or, first of all, he would return the patient with advice to the physician and, before [40] arriving at a conclusion as to what advice he would have to give, he would certainly determine whether or not there was evidence of male climacteric and that would involve determination of the secretion of male hormone.

Q. You are bringing that last into the picture for this reason, to see whether or not there was a deficiency of male hormone in the individual?

A. Yes.

Q. I think we can agree, can't we, that a male hormone product will not benefit a person who is not suffering from a deficiency of male hormone?

A. That is right.

Q. And so it would only be then, if a man was

(Testimony of Clinton H. Thienes, M.D.)
actually suffering from a deficiency of the male hormone, and the urologist's diagnosis had been that he found no evidence of carcinoma of the prostate, that the general practitioner would prescribe testosterone for him?

A. Are you assuming these laboratory tests I have talked about, too?

Q. Yes.

A. Then, I think the doctor would give testosterone in one of its forms.

Q. Let's assume, say, that the urologist didn't conduct a laboratory test. Doesn't it often happen that the general practitioner will, after receiving a negative report [41] on prostatic cancer from the urologist, prescribe testosterone for the man for a certain period of time, to see whether or not any relief accompanies the administration of it?

A. No. I think today the general practitioner would want to know for sure whether this was a case of climacteric or not before he would give the testosterone.

Q. Is it your opinion that the average general practitioner will require a laboratory test before prescribing testosterone for a patient who is complaining of symptoms which seem to be associated with male climacteric?

A. I don't know what you mean by the average general practitioner.

Q. Just that.

A. There ain't none. There is no such animal.

Q. There is no average doctor? A. No.

Q. Well, would you say that the majority of doc-

(Testimony of Clinton H. Thienes, M.D.)

tors, general practitioners, would require a laboratory test prior to a prescription of that?

A. I think today they would.

Q. Is that simply your thought or just what is it based on?

A. It is based upon knowledge of medical literature largely, and the literature today is such that most doctors are aware of the danger of symptoms and prostatic cancer, by [42] giving testosterone preparations, and therefore they are very cautious about it.

Q. I now go to another phase. Can you say as a fact that it has ever been demonstrated by clinical tests that testosterone was responsible for a prostatic cancer?

A. The testosterone has been responsible for prostatic cancers growing rapidly, whatever they were diagnosed. I would not say that testosterone will cause a cancer to develop. I mean by the word "develop" to be actually started, and the cells which become cancer cells to be produced from normal epithelium near the prostate, but, once the cancer is started, then the testosterone has been known to exaggerate it.

Q. By clinical proof it has been known to exaggerate it? A. Yes.

Q. Or is that simply an assumption or an inference, rather, from other things? Can you give me any example in which it was clinically proven that testosterone accelerated the growth of a prostate cancer?

(Testimony of Clinton H. Thienes, M.D.)

A. I don't remember any specific instance at the moment.

Q. You are familiar with at least some of the literature that has discussed the subject, are you not? A. Yes. [43]

Q. And isn't it a fact that that literature simply says to this effect, in substance, that testosterone may cause the acceleration and the growth of a prostatic cancer; that it has been suggested that it may cause the acceleration and so on; and that in none of the literature has any investigator reported that he was able to prove medically that it did so?

A. That isn't my interpretation of the literature.

Q. Can you tell me, Doctor, what literature you have reference to that leads you to that interpretation?

A. I can't point to any specific article at the moment. There are a number of papers of a man named Huggins particularly that I recall, that have shown the effect of testosterone upon prostatic cancer. [44]

Q. (By Mr. Elson): And Huggins, as I understand it, and you may correct me if I am wrong, was one of the few investigators who did any amount of work on that subject? A. That is right.

Q. And is there anything, in any of the reports of Huggins, as you recall it, in which he reported that a carcinoma of the prostate had been clinically proven by him to have been accelerated by the administration of testosterone?

A. I don't recall that.

(Testimony of Clinton H. Thienes, M.D.)

Q. As a matter of fact, isn't your recollection that Huggins reported that because of his experience in castrating some 20 males and watching the results following that castration, that he was of the opinion that testosterone may accelerate the growth of a prostatic cancer?

Mr. Danielson: I would like to interpolate one question, your Honor: To which Huggins or what Huggins is counsel referring?

Mr. Elson: I think there is only one, isn't there?

The Court: I assumed that they were in agreement, as between counsel and the witness, as to Huggins. I don't know him.

Mr. Danielson: For the sake of the record, I would like to have it shown what Huggins he is referring to.

The Court: Very good. [45]

Q. (By Mr. Elson): Do you know of any other Dr. Huggins, Dr. Thienes, who is mention reputably in the literature with regard to experiments having to do with prostatic cancer?

A. I do not. The one I am referring to is now Professor of Surgery at the University of Chicago.

Mr. Danielson: If your Honor please, we intend to bring Dr Huggins to the witness stand in this particular case, at a later time.

The Court: Let us connect that up, with the time that Dr. Huggins reported.

Q. (By Mr. Elson): Do you remember when he wrote or rendered his report?

A. He is still reporting, but the earliest reports

(Testimony of Clinton H. Thienes, M.D.)

are several years ago. I would hesitate to say the particular number of years.

Q. To refresh your memory, was it in 1939?

A. I would hesitate to say.

Q. By the way, while I am trying to find something here, you have stated what your interpretation of the consensus of medical opinion is, or the effect that methyl testosterone may have on sterility, in causing sterility, and also that alpha estradiol accelerates cancer of the breast, cervix and uterus, am I correct? A. Yes. [46]

Q. Well now, in arriving at what you understand to be the concensus of medical opinion, you take into consideration the reports, writings and investigations of others, do you not?

A. That is right.

Q. And those reports, investigations and so on are found not only in medical books, but they are found in The Journal of the American Medical Association, the Urologic and Cutaneous Review, the Journal of Clinical Endocrinology and others, am I correct? A. Yes.

Q. And based upon what you read as reported by others in those, in that literature and other comparable publications, coupled with your own experience and your study generally, you then arrive at what you believe to be the concensus of opinion on this, that or the other subject, am I correct? A. Yes.

Q. And that is true, isn't it, with all doctors that you know of? A. Yes, I think so.

(Testimony of Clinton H. Thienes, M.D.)

Q. Isn't it also true that other doctors, and let us say all of them, with the qualification that they are competent, intelligent, interested men in their profession, keep abreast of what to do and what not to do with respect to their [47] patients, by experiences in their own practice plus the reports of others such as I have mentioned?

A. Yes, that is true.

Q. And that, with that experience and also taking into consideration the reports of others, they will with their patients try out on them, all things being equal, the method of administration or whatever it might be as reported successfully by one of these other investigators?

A. That is often true.

Mr. Elson: Well now, if the court will bear with me here a moment.

Q. Oh, by the way, in the literature that you have read which discusses the use of testosterone, is it your recollection that in practically all of those articles the writer warns against the use of testosterone when cancer of the prostate may be indicated? A. Yes.

Q. You are sure of that?

A. Most of the current writings, yes.

Q. Now, I think you stated, Doctor, that in the case of prostatic enlargement, a suspicion would arise in your mind whether or not a carcinoma was present? A. Yes.

Q. Do you know of a doctor by the name of Walter M. Kearns of Milwaukee? [48]

(Testimony of Clinton H. Thienes, M.D.)

A. No, I don't know him.

Q. You have never heard of him?

A. I may have heard of him. I don't recall his name at the moment.

Q. Are you familiar with the name of a doctor by the name of Harry Benjamin, who wrote at least one article for the Urologic and Cutaneous Review in 1946? A. I don't remember it.

Q. The subject of his article was A Contribution to the Endocrine Aspect of the Impotence Problem, a Report of 39 Cases. His name is Dr. Harry Benjamin, M.D., New York City. That appeared in the Urologic and Cutaneous Review, Volume 50, March, 1946, page 143, and I am going to state to you what he stated on that page; under his title of Summary Conclusions and General Remarks: "Since large amounts of the hormone may suppress gratuitous function temporarily and thus aggravate the sexual inadequacy or may stimulate growth of dormant cancer cells in the prostate, doses not higher than 10 milligrams testosterone propionate twice or three times a week seem advisable."

Now, coming back to your previous statement, you stated, I believe, that you had no recollection of any investigators reporting that it was only the testosterone which might accelerate cancer growth, and that there had been no reported case of—that you did not know of any such qualification, [49] that I bring that to your attention and ask you, after my having read that to you, is your opinion as previously expressed in any wise altered?

A. No.

(Testimony of Clinton H. Thienes, M.D.)

Q. In other words, you don't agree with it?

A. I don't agree with your interpretation of what he says.

Q. Well, Doctor, I read it. You can read it, if you wish. I read it right out of the article.

A. Well, you are inferring——

Mr. Danielson: I object to this as argumentative. The doctor has stated his opinion and his reasons therefor.

Mr. Elson: Well, I am willing to let it stand as it is. [50]

* * *

The Court: Well, that will be all right. Just before we do adjourn, I would like to get a few little wrinkles straightened out. You must know that a great deal of this technical matter is new to the court, I mean the medical and the clinical matter.

May I ask you, Doctor, your testimony, as I get it, is that any case of enlargement of the prostate gland is a suspicious thing with relations to cancerous possibility? [51] A. Yes.

Q. Or even probability?

A. Well, there is a certain probability.

Q. The practice, then, I believe that of so many physicians is to undertake to alleviate the enlargement, reduce it by some form of massage or some similar treatment?

A. Well, only under certain special circumstances would massage be used. Where the prostate

(Testimony of Clinton H. Thienes, M.D.)

is large enough to produce serious symptoms, usually operation is advised.

Q. Massage would be detrimental if there was a cancerous condition? A. That is right.

Q. Now, tell me again (I think you have gone over this), if you can very briefly: How has it been determined that testosterone promotes the growth of cancer cells in the prostate and in the breast?

A. Well, testosterone does not promote cancerous growth in the breast. That is the action of the extrogens that does that——

Q. Oh, yes.

A. ——but, there are various types of evidence to support the conception that testosterone stimulates cancer of the prostate, it hurries its development; for instance, from a statistical point of view, the profession interested in this field are aware of the rate, the usual rate of development of [52] cancer of the prostate. Whenever testosterone administration has been associated with prostatic cancer, it has been shown that the development has been much more rapid than would be anticipated from knowledge of the development of the prostate when testosterone is not administered, for instance.

The Court: Well, that has been the index?

A. That is the one that comes to my mind at the moment, yes. There are other criteria which I assume other witnesses will enlarge upon. [53]

* * *

(Testimony of Clinton H. Thienes, M.D.)

Q. (By Mr. Elson): Doctor, I think you testified on direct examination that the concensus of opinion was that methyl testosterone would cause sterility? A. Yes.

Q. Now, would the amount of dosage have anything to do with whether or not sterility would be caused?

A. Sterility has been caused by the usual doses.

Q. Meaning what?

A. Oh, 10 to 25 milligrams repeated.

Q. How often?

A. Daily or less frequently.

Q. Now, in arriving at that concensus of opinion as you interpret it, I take it that you, among other things, consulted and have consulted the writings and reports of other investigators appearing in one or more of the publications that I mentioned this morning? A. Yes.

Q. In arriving at that concensus, did you give any consideration [54] to an article appearing by Laurance W. Kinsell, in the Journal of Clinical Endocrinology, December, 1947, entitled "Spermatogenesis in a Pan-hypopituitary Eunuchoid, as the Result of Testosterone Therapy"? Did you?

A. No; I don't remember that article.

Q. Now, if I told you that in that article that investigator reported as follows: "We wish, at this time, to report testosterone-induced spermatogenesis in a 25-year-old male showing both laboratory and clinical evidence of pan-hypopituitarism, using the term in a very broad sense," would that report of

(Testimony of Clinton H. Thienes, M.D.)

that investigator influence you at all in your opinion?

A. Not at all. That is quite a different situation.

Q. I referred this morning in asking a question in connection with your arriving at the concensus of opinion to an article by Dr. Walter M. Kearns in the Wisconsin Medical Journal, entitled "Testosterone." Or did I? Was that one of them? Whether it was or not, let me put it this way. In arriving at your interpretation of that concensus, did you give any consideration to or read the article entitled "Testosterone in the Treatment of Testicular Deficiency and Prostatic Enlargement," by Walter M. Kearns, M.D., Milwaukee, appearing in Volume 40 of the Wisconsin Medical Journal, October, 1941, at page 928, which read as follows:

"Clinical reports indicate equally amazing results when the order is reversed and estrogens are given to the male. Charney has recently brought about correction of abnormal libido in a male sexual criminal by the administration of large doses of stilboestrol, the synthetic estrogen"—well, I don't know what that word means. "There also occurred a cessation of spermatogenesis, with degeneration of the germinal epithelium as proved by testicular biopsy. In this instance testosterone might have accomplished the same result, as depression of spermatogenesis has frequently been demonstrated after the administration of huge doses of testosterone to normal persons"? [56]

After that article has been read to you, does that

(Testimony of Clinton H. Thienes, M.D.)

in any wise alter your opinion to the effect that, as I understand you to say, in most cases the normal dose of 10 milligrams, maybe one or two tablets per day, of testosterone will cause sterility?

A. I don't think I said it that way.

Q. I didn't mean to misquote you.

The Court: 10 to 25 milligrams.

Q. (By Mr. Elson): All right; 10 to 25 milligrams. A. Let me read that. May I?

Mr. Danielson: What page are you reading from?

Mr. Elson: It is on page 928.

A. This does not alter my opinion. His statement that huge doses produce it in normal persons is not contradictory to what I said.

Q. (By Mr. Elson): In other words, you believe——

A. I believe that the ordinary doses also have been known to do the same thing.

The Court: While you are dealing with that, make it a little more comprehensive to a layman, will you? I get the sense of it not too clearly.

Mr. Elson: Your Honor, I will be very frank about it. What I am driving at is this: The doctor has testified that it was his interpretation of the concensus of opinion that testosterone in normal doses say of 10 to 25 milligrams [57] per day would cause sterility in the persons who took it.

The Court: Did you make that conditional?

Mr. Elson: I didn't understand it to be so.

The Court: Do you mean that was just a flat statement?

(Testimony of Clinton H. Thienes, M.D.)

The Witness: I don't mean it would happen to everybody but it does produce sterility in a large number of individuals to make it a dangerous thing if testosterone is given without careful control of the patient.

Mr. Elson: For the purpose of the record, I move to strike the portion of the witness' statement that it would make it dangerous and so on. That is a conclusion for the court to determine at the end of this case.

The Court: He is giving nothing more than his opinion, as I take it.

Mr. Elson: What I am proposing to show here is that as a part of that concensus as he has stated are the writings and the investigations of others, such as these doctors whose articles I have referred to, and that in the articles that I have called to his attention and those which I propose to call to his attention I propose to show that what he says is not a fact necessarily, and that in many cases of spermatogenesis or, in other words, an increase in fertility in the individual is accomplished by the administration of testosterone.

The Court: Very good, but as I understand it, the witness' [58] testimony is that from his observation and experience, discussion and reading, he has formed one opinion. Now you are testing him as to an opinion expressed by others and asking him if that has any tendency to change his view. Thus far, he has answered no. You may go ahead. [59]

Q. (By Mr. Elson): Now, Doctor, what do you mean by sterility?

(Testimony of Clinton H. Thienes, M.D.)

A. Inability to reproduce.

Q. Now, do you mean by your testimony that testosterone will cause sterility, am I correct, in a majority of persons or a large number?

A. A fairly large number, yes.

Q. That that sterility is going to be permanent, even though the person discontinues or the doctor quits prescribing testosterone?

A. No, not necessarily.

Q. As a matter of fact, it is only a temporary condition, is it not? A. In many cases, yes.

Q. And isn't it true that from either your experience or your reading, that in many cases, spermatogenesis, or fertility has been increased in the individual to whom testosterone has been administered and prescribed?

A. In certain special endocrine disturbances, yes, such as you describe there, which was one of the unusual types of endocrine disease.

Q. Now, when a person goes to a doctor and the doctor prescribes testosterone to him, I take it that the doctor knows that it may cause temporary sterility or a decrease in the sperm count? [60]

A. Yes.

Q. Well, then, the effect is the same, isn't it, whether a doctor prescribes it or whether the person tries it without prescription? A. No.

Q. Why not?

A. Because the doctor will know when it is safe to continue or discontinue, when it is proper

(Testimony of Clinton H. Thienes, M.D.)
to direct or to discontinue, but the individual who does not have medical advice doesn't know.

Q. Well, as a matter of fact, the ordinary person who would be taking the testosterone is a person in his middle age, isn't it?

A. I presume so, yes.

Q. And do you think that sterility with a person 45 or 50 or 55 or 60 years old is an important factor?

A. Yes, sir.

Q. In what way?

A. I think any man would be willing to answer that. One thing it would have a very bad psychological effect upon an individual.

Q. Well, isn't it a case of being willing to accept the benefits of a product such as testosterone and giving up fertility at least for the time being?

A. Yes, but I don't think a person not medically trained knows when it is safe to make that decision, and there are many other circumstances that have to be taken into consideration.

Q. In your opinion, would a doctor who was prescribing testosterone for a person and who found that it was causing him to be sterile, but who also found when he took him off of testosterone, the same bothering symptoms would return, generally quit prescribing testosterone?

A. Well, the proper indication for testosterone would in a large number of cases be associated with at least a relative sterility.

When testosterone is properly given, sterility or

(Testimony of Clinton H. Thienes, M.D.)

temporary or at least a degree of sterility is often present.

The person who diagnoses his own condition as something requiring testosterone, the chances are that he will not be the type of person that needs it. Therefore, he would not be, ordinarily, sterile and he would produce sterility in himself, which is quite a different circumstance from the type of patient that the doctor is going to treat.

Q. A moment ago you spoke about testosterone being dangerous, I believe. A. Yes, I——

Q. Unless given under the prescription of a physician?

A. Under the guidance of a physician, yes, and prescription.

Q. Now, on that subject of danger, do you consider testosterone [62] any more dangerous than bromo seltzer? A. Yes.

Q. Isn't it a fact that bromo seltzer is sold over the counter at soda fountains?

A. I am sorry to say that it is.

Q. And isn't it a fact that there are people in mental institutions right now that are there because of bromides that they have taken, in excess amounts?

A. Well, I don't know the fact. I know that people go to mental hospitals from overdoses of bromides. I don't know whether there are any bromo seltzer bromide poisonings today in a hospital.

Q. Well, an excess of bromides can cause mental derangement, can it not? A. Yes.

(Testimony of Clinton H. Thienes, M.D.)

Q. And bromo seltzer contains bromides?

A. That is right.

Q. And you are familiar with the fact, are you not, that there are many, many people that take bromo seltzer practically every day, if not certainly every day?

A. Yes, there are such people.

Q. Will not an excess of, take the product Alka Seltzer, tend in the long run to cause alkalosis in persons that are taking that excess?

A. Yes. [63]

Q. And that is sold over the counter, too?

A. Yes.

Q. Without prescription? A. Yes.

Mr. Elson: That is all. Wait just a moment. Doctor, I have one other question:

Q. In your experience, did I understand you to say that you had engaged in private practice?

A. I have.

Q. And having patients of your own or consulting? A. Both.

Q. How long have you been in private practice, in the handling of patients of your own?

A. I had a private office from 1942 until September of last year.

Mr. Elson: I have no further questions.

Redirect Examination

By Mr. Danielson:

Q. Just to clear up a couple of points, Doctor:

(Testimony of Clinton H. Thienes, M.D.)

What do we mean by palpation, Doctor? Palpation.

A. Palpation in medicine, medical parlance, is the examination of a patient by feel.

Q. An examination, a palpation of the prostate, would mean feeling of the prostate?

A. Yes. [64]

Q. What is the meaning of metastaisis, Doctor?

A. A metastaisis of a cancer is a cancer that has developed at a position different from the origin by some of the cancer cells at the site of origin, breaking loose from the original tumor and being transported to some other part of the body by lymphatics or blood, so, a metastatic cancer is a cancer at some part of the body different from the site of the original cancer.

Q. Now, you have mentioned palpation of the prostate. Is it possible, Doctor, to diagnose a carcinoma of the prostate by palpation at an early stage? A. Yes.

Q. At an early enough stage so that beneficial therapy can be administered? A. Oh, yes.

Q. Could that be early enough to avoid aggravation by the use of testosterone?

A. I am not sure that I am following your question there.

Q. At such a stage, when you could diagnose the carcinoma by palpation, would that be early enough so that it would be a contra-indication to the use of testosterone? A. Yes.

Q. Now, certain symptoms were mentioned in your cross-examination, namely, flushes, sweats,

(Testimony of Clinton H. Thienes, M.D.)
nocturia, inability to [65] concentrate, irritability, in males of about 50 years of age. Would those symptoms be present in diseases or conditions other than hormone deficiency?

A. Yes, in most instances those symptoms are due to something other than hormone deficiency.

Q. Could you explain that, please, or give an example?

A. Well, in exophthalmic goiter or toxic goiter these symptoms would occur, in fatigue states, in anxiety states, they are common in tuberculosis, you will find that type of symptom complex.

Q. Would those conditions respond favorably to a testosterone therapy? A. No.

Q. What would be the effect of such therapy, in such cases?

A. It would be the same as in any other patient, that is, there would be the danger of producing sterility; or if there were a cancer present, of exaggerating it, cancer of the prostate.

Q. Upon the basis of your experience, practice, learning and education, Doctor, have you found—do you know whether persons in their late forties or fifties, persons with these specific symptoms, tend to diagnose them themselves?

A. Very often.

Q. What is the usual result of that, Doctor?

A. Well, they sometimes try to medicate themselves, treat themselves, such as buying testosterone, thinking that they have a deficiency of testosterone secretion, when they have one of these other diseases,

(Testimony of Clinton H. Thienes, M.D.)

and they would try to treat themselves in some instances to the point where the disease process has gone so far that it is difficult to treat satisfactorily.

Q. But you have mentioned, Doctor, that the testosterone is of therapeutic value where there is a deficiency in testosterone in the normal supply in the body? A. Yes.

Q. How is it determined whether or not there is an adequate supply of natural testosterone?

A. The only sure way that I know is to make hormone tests.

Q. And how are they done, generally speaking?

A. Well, it is a laboratory procedure.

Q. Does it require any special training?

A. It requires very special training.

Q. Now, Doctor, in connection with some of the literature which was brought to your attention, there was a statement in substance that the use of testosterone may produce a certain effect. Doctor, what is the significance of the word "may" in scientific and medical literature of that type?

A. Very often a physician in writing a paper, or in [67] giving a talk or in lecturing to students, will use the word "may" in the sense that a given situation occurs in let us say 10 per cent or 20 per cent of a given type of circumstance; so that a particular individual then has that probability of fitting in with the described condition and so the doctor will use the word "may" in that circumstance, meaning that there is a probability that this

(Testimony of Clinton H. Thienes, M.D.)

particular patient may respond in a certain way or have a certain condition, that is, he uses "may" in the terms of based upon known frequency of occurrence.

Q. There was a question asked, Doctor, to the effect that the use of testosterone might be it meant a choice of giving up a certain amount of fertility, in exchange for some benefits to be derived from the use of testosterone, to which you replied in effect that is true, but other circumstances must be taken into consideration. What would be such circumstances, Doctor?

A. Well, I think that the most—at least the thing that comes to my mind is the natural desire of every male to retain his potency; he may wish another child.

Q. Would the toxic effect have any bearing at that point? A. Toxic effect of what?

Q. Of the testosterone?

A. I don't see a relation. [68]

Q. With relation to carcinoma of the prostate, for example?

A. Well, of course, he would not be interested in developing a carcinoma of the prostate. I did not have that in mind, in my answer at the time.

Q. Now, Doctor, there was an article by Dr. Walter M. Kearns, "Testosterone in the Treatment of Testicular Deficiency," and prostatic enlargement was mentioned, and a portion was read therefrom. I direct your attention to the statement which was read, "Cherney has recently brought

(Testimony of Clinton H. Thienes, M.D.)

about the correction of abnormal libido in a male sexular criminal by the administration of large doses of stilboestrol, the synthetic estrogen."

What is stilboestrol, Doctor?

A. Stilboestrol is a synthetic or artifically prepared estrogen.

Q. That is one of the female hormones, is that correct?

A. It has the effects of the natural female hormones, but it is an absolute, entirely artificial preparation. It is a laboratory preparation.

Q. And in the same sentence he uses the expression "abnormal libido." What is the significance of that, in plain English? A. Libido? [69]

Q. Is it abnormal?

A. Well, it might be a number of things. Libido itself is sexual desire and there are various and sundry types of abnormal libidos.

Q. Then, in the same connection, in connection with the same experiment, was the phrase there also occurring, "a cessation of spermatogenesis." What is the significance of that?

A. A spermatogenesis or cessation of spermatogenesis is the ceasing or stopping of the manufacture of spermatocytes, or as we ordinarly call them, sperm cells.

Q. Is there any respect in which that does not agree with your position that the use of hormones might decrease fertility at least? A. No, no.

Q. Now, there is one more expression in this same article, at the bottom of page 928, of which I quote:

(Testimony of Clinton H. Thienes, M.D.)

"One of the contra-indications for the administration of testosterone is the desire in a young man simply to enhance his sexual power. There is apt to occur not only a lessening of the sexual power but a depression of spermatogenesis as well."

Does that in any respect differ from your opinion, Doctor? A. Not at all. [70]

Mr. Danielson: No further questions.

The Court: Is there any recross?

Mr. Elson: That is all.

Q. (By the Court): However, Doctor, how would a doctor (by that I mean a physician, the ordinary family physician) determine approaching sterility in a case?

A. Well, there are several factors that he would take into consideration. One is the inability of the man and his wife to have children.

Q. Yes.

A. Second, the lack of sexual potency, the inability to perform the sexual act and, third, the actual examination of the seminal fluid to determine the number of spermatozoa present and the degree of motion. [71]

* * *

The Court: As to the progressiveness of sterility, it would require a chemical examination from time to time, would it?

A. Not necessarily a chemical examination for sterility, but it would require an examination of

(Testimony of Clinton H. Thienes, M.D.)
the seminal fluid from time to time. That is a laboratory procedure.

The Court: I don't have it in mind now and you may have told it but, if you did, I have lost it. Just how was it determined that the use of this drug would cause sterility?

A. Well, by the procedures which I have just outlined. Particularly, the laboratory procedure is the examination of the sperm. I am wondering if you are thinking of the diagnosis of male climacteric or a failure of secretion of testosterone.

The Court: Perhaps so but I got the impression firmly fixed in mind that you testified that the use of testosterone would be very likely to cause sterility in many cases. What I am inquiring is how was that determined.

A. The frequency with which this occurs, of course, is a matter that had to be worked out in a well-organized clinic, where a large number of patients could be studied.

The Court: Patients who were using it from day to day?

A. Yes, and under the doctor's direction.

The Court: And it was in that manner determined that it [72] did have that effect?

A. That is right. That had, of course, been discovered in the experimental animal before it was known in man. It was the results of experimental animal laboratory work that led the doctor to examine his patient to determine whether the same effects were happening in the patient.

(Testimony of Clinton H. Thienes, M.D.)

The Court: And it was also determined by the type of libido?

A. That testosterone would affect the libido in the individual who has a deficiency in secretion of testosterone; yes. I am not sure that I understood your question. Testosterone has an effect upon the libido but we don't study libido by examining the sperm.

The Court: That is all.

Mr. Danielson: That is all for the government.

Recross-Examination

By Mr. Elson:

Q. Doctor, what is the cost of a laboratory examination to determine whether a person is sterile or not? I mean, if a person goes to a doctor for some reason and the doctor is of the belief that testosterone might be the thing for him and so he has an examination conducted to determine whether the man is sterile, what would be the cost of such examination?

A. Just to examine the sperm would cost, I think, in the neighborhood of $5.00. [73]

Q. I am speaking of the total cost.

A. You will have to repeat your question. I am afraid I didn't understand it.

Q. Would the doctor do it himself?

A. The doctor could do it himself, certainly, if he knew how.

Q. In connection with the examination for determining whether or not there is a hormone de-

(Testimony of Clinton H. Thienes, M.D.)

ficiency, before prescribing testosterone, what would be the cost of that procedure?

A. Fifteen to twenty-five dollars.

Q. That would be a sample of the urine, would it not? A. Yes.

Mr. Elson: That is all.

Mr. Danielson: That is all.

Dr. Warren Nelson, please. [74]

WARREN NELSON, M.D.

a witness called and sworn for the government, testified as follows:

The Clerk: Will you state your name?

A. Warren O. Nelson.

Direct Examination

By Mr. Danielson:

Q. Where do you live, Dr. Nelson?

A. Iowa City, Iowa.

Q. And what is your present occupation?

A. I am professor of anatomy in the College of Medicine at the University of Iowa.

Q. Of what schools are you a graduate, Doctor, and in what years and what degrees do you have, please?

A. In 1928, the Augustana College of Augustana, Illinois, Bachelor of Arts; 1929, University of Iowa, Master of Science, and, in 1931, New York University, Doctor of Philosophy.

(Testimony of Warren Nelson, M.D.)

Q. What was your specialty or major in your Doctor of Philosophy, Dr. Nelson?

A. Physiology and anatomy, a combined program.

Q. What post-graduate training have you had?

A. For two years, I studied as a National Research Council fellow at the University of Chicago with Dr. A. J. Carlson and Dr. Carl Moore.

Q. And what type of training did you receive there, [75] please?

A. I continued my training and endocrine studies, endocrinology, with Dr. Carlson and Dr. Moore.

Q. And what scientific or medical societies, if any, are you a member of?

A. I am a member of the American Association of Anatomists, the American Biological Society, the American Cancer Society, the Association for the Study of Internal Secretions, the Society for Cancer Research, the Society of Experimential Biology and Medicine and the Johnson County Medical Society, which is our local society.

Q. You have testified, Doctor, that you are presently professor of anatomy at the University of Iowa Medical College, is that correct?

A. Yes, sir.

Q. How long have you been so affiliated?

A. I have been at the University of Iowa five years.

Q. Did you previously have any teaching affiliations?

(Testimony of Warren Nelson, M.D.)

A. Yes; at the College of Medicine at the University of Missouri.

Q. What was your capacity there?

A. I was assistant professor of anatomy there. I held the same post, assistant professor of anatomy, at Yale University, College of Medicine, and I was professor of anatomy and head of the department at Wayne University, College of [76] Medicine, at Detroit.

Q. How long were you there in that capacity?

A. Two years.

Q. In what fields do you teach medical students?

A. Human anatomy and endocrinology.

Q. Are those the fields in which you specialized, Doctor? A. Yes, sir.

Q. Do you make a practice, Doctor, of studying and reading the literature in your field of endocrinology? A. Yes.

Q. And do you from time to time confer with and discuss with other scientists and doctors as to this subject matter?

A. Yes, sir; very frequently.

Q. Will you explain the meaning of the term endocrinology, Doctor?

A. It is a study of the endocrine glands or of the glands of internal secretions. These are certain glands of the body whose products are released direct into the blood stream.

Q. Will you name some of them?

A. The testes, which are under discussion, the

(Testimony of Warren Nelson, M.D.)

ovaries, the pituitary, the gland in the head, the adrenals, the pancreas and the thyroid. [77]

Q. About how many scientific papers have you had published on the subject of endocrinology?

A. Something on the order of 150, I believe.

Q. Would you name a few of the representative publications in which they have been published, please?

A. The Journal of Clinical Endocrinology, Endocrinology, American Journal of Anatomy, Anatomical Record, Proceedings of the Society of Experimental Biology and Medicine.

Q. Have some of these papers related to the function of the testes? A. Yes.

Q. About how many, Doctor?

A. Oh, 25 to 35, I would estimate.

Q. Have you done any investigation into the use of testosterone? A. Yes.

Q. And its effect on the function of the testes?

A. Yes.

Q. How extensive has been your research in that line, Doctor?

A. It has covered a period, I would say, of 15 years. In the days before we had testosterone as a purified chemical, we were using extracts of bull's testes or human urine, on up to the present time, when we have highly purified products. [78]

Q. What has been the object of this research, Doctor?

A. To determine the function of the testes and the factors which control the function of the testes.

(Testimony of Warren Nelson, M.D.)

Q. Has any of this been to determine the effect of testosterone n the testes? A. Yes.

Q. Has any effort been made by you to determine the effect of testosterone on other parts of the body besides the testes? A. Yes.

Q. Doctor, in conducting your investigations, has it been your policy to consult with medical doctors on the staff of your university and assisting them in making diagnoses and recommending treatment in cases of testicular disfunctioning or other endocrine conditions?

A. Yes; our own medical staff and the medical staffs in other universities as well.

Q. Will you kindly describe to the court, Doctor, the investigations of this nature that you have conducted?

A. Is it at this point that you would like to have me——

Q. Will you kindly describe to the court, Doctor, on the basis of your education, your training and experience, your study, your consultations and discussions, your clinical and laboratory research, the sum total of your experience along this line, particularly the effect of testosterone on [79] the testes or other parts of the anatomy? What is the effect of testosterone?

A. These studies have embraced not only studies on human patients but also studies on experimental animals. The forms of procedure or general procedure that we have followed in the case of the studies on human testes is to obtain a sample, a

(Testimony of Warren Nelson, M.D.)
biopsy, of the testes, in fact both testes, prior to treatment, and then to administer the hormone over a definite period of time, at the end of which a second biopsy would be obtained and compared with the first biopsy. At the same time, studies would be made upon hormonal levels of the urine and these would include studies of the byproducts of the male sex hormone, testosterone, and the levels in the urine of hormones called gonadotrophins. These are substances produced in the pituitary gland, a small gland in the head. These gonadotrophins are all essentially a normal function of the testes. The injection of testosterone will inhibit the activity of the pituitary in the production of these gonadotrophins and this will, in effect, bring about a condition of hypophysectomy. That is a condition in which the pituitary is removed or absent. The same would be true of estrogen; it will inhibit the production of these gonadotrophins and that is a definite function of these testes normally. The result is a lowered production of spermatozoa and a lowered production of the hormones of the testes. [80]

Q. In this inhibition of the gonadotrophins, Doctor, are you referring to the natural supply of testosterone within the body or that administered from some independent source?

A. In this case, I am referring to the administration of testosterone. However, I think it is proper to say that in the normal functioning of the pituitary testicular axis there is an interplay be-

(Testimony of Warren Nelson, M.D.)

tween the testicular hormones and the pituitary hormone. As the pituitary hormone drops, the testicles would no longer be stimulated properly and thus the level of the testicular hormone testosterone would drop and the pituitary would then go into greater activity. It is an action like a thermostat. When the heat drops, the thermometer there records it and turns the furnace on. As the testes hormone level drops, the pituitary is turned on to produce more gonadotrophins. However, if the level of the testosterone gets too high, then the activity of the pituitary is lessened just as when the temperature in the room gets too high the furnace is turned off.

Q. In other words, is this correct, that the gonadotrophins have some effect on the testes?

A. That is right.

Q. And their effect is to do what?

A. To stimulate the testes to produce spermatozoa and to produce testosterone. [81]

Q. And then, when the testosterone level increases, what effect does that have on the pituitary?

A. That inhibits the pituitary's activity in the production of these gonadotrophin hormones and thus would decrease the activity of the testes both in the production of the spermatozoa and in the production of testosterone within the testes.

Q. For how long a time would this inhibition last, more or less?

A. Certainly for the duration of treatment. How much beyond that it is difficult to say.

(Testimony of Warren Nelson, M.D.)

Q. Have you, as a result of your experiments and studies made any determination as to what ultimate effect that has upon the testes?

A. In the case of human testes, the result will depend a great deal upon the condition of the testes at the time the administration of testosterone is begun. If the testes are entirely normal, as determined by this pretreatment biopsy, the effect is less marked, though very evident, than in the case of testes which are not entirely normal, which have undergone certain changes, particularly in the connective tissue around the tubules of the testes. Testes that have that type of damage are very definitely and rapidly damages when testosterone is administered.

Q. Is this damage a permanent effect? [82]

A. I cannot as yet answer that question to my own satisfaction but I think probably not unless the damage before treatment in the testes is present and treatment is continued for, say, five or six months.

Q. Doctor, have you made in connection with these experiments any determinations as to sperm levels?

A. Spermatogenesis is affected by the administration of the testosterone. However, I am reluctant to place complete dependence on sperm counts unless many, many of them are taken. There is quite a fluctuation from day to day or often week to week in the same individual and many counts must be taken to establish a norm. I feel that a

(Testimony of Warren Nelson, M.D.)

sample taken and studied with greatest histologic detail reveals much more than do a few.

Q. On the basis of your experiments and your education and training and research, do you have an opinion as to the effect of testosterone therapy on fertility or sterility?

A. Yes; at the present time I would say all evidence that we have been able to accumulate indicates that a level of testosterone which will have an effect on the testes, and by that I mean 20 to 25 milligrams a day, indicates it will cause damage to the testes, the extent of the damage being determined by the pretreatment condition of the testes.

Q. On the basis of your research, Doctor, do you have an opinion as to the frequency of damage to the testes in men [83] in their fourth or fifth decade?

A. Well, as men get older, the testes show the ravages of time and they are more prone to be in an atrophic condition, so that a man in the fifth or sixth decade of life would be more likely to have testes which are already showing some damage and, therefore, be more susceptible to the damaging influences of testosterone.

Q. Doctor, as to this information you have just given us, do you include this in your teaching to your medical students in whole or in part?

A. Yes; in general essence, we give them these details, though I have had more occasion to dis-

(Testimony of Warren Nelson, M.D.)

cuss these matters with medical societies and medical groups in various parts of the country.

Q. Doctor, in connection with your discussions with medical societies and medical groups, have you had any method of illustrating and establishing the interplay of the various secretions, as you have just described them to us?

A. Yes. We commonly use what are known as lantern slides, with pictures of either diagrams or histologic material which has been collected in the course of the studies.

Q. Did you bring some of those slides with you, Doctor? A. Yes, sir.

Q. Were they prepared in connection with this case or in connection with your regular work? [84]

A. They were prepared in connection with my regular work and have been used many times in other connections.

Q. That was before you heard of this case, is that correct? A. Yes, sir.

Q. Did you bring any of those slides with you, Doctor? A. Yes, sir.

Q. Were they made by you or under your supervision and direction? A. Yes, sir.

Q. And are they an accurate portrayal of that which they purport to portray?

A. I think so.

Q. Would it help, Doctor, to explain the results of your experiments by projecting them?

A. I think some of the points I have attempted

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to make could be a little more graphically obtained if they were used.

Mr. Danielson: Your Honor, we have in court various of these slides that Dr. Nelson has referred to. We also have a slide projector set up and a screen here. We should like to offer them, your Honor, at the present time, subject to cross-examination as we go along, if counsel wishes, and subject, of course, to the motions made earlier today by counsel for the defense to strike in the event they do not apply. With the permission of the court, we should like to project them. [85]

The Court: Very well. Proceed.

A. If we can have the lights off, we can use the wall and it will be more evident, if that is permissible.

Mr. Neukom: Oh, surely.

A. That is backward. The red spot should be on top and to the right. Just to locate the area of the testes and some of the things it affects, this is a saggital section through the body, the testes in the scrotum, and some of the structures which are affected by testosterone are this sperm duct, the epididimus passing up here, the prostate, which is this area here connected with the bladder, the seminal vesicles, which also contribute to the seminal fluid, and then the penis. The next slide, please. Oh, yes; if there are any questions, please ask them.

Q. If there are any questions, you may ask them.

Mr. Elson: I haven't in reference to that slide.

A. This is a diagrammatic section through the

(Testimony of Warren Nelson, M.D.)
testes, indicating tubules which produce the sperm. And they can be seen in orderly progression from the basement membrance here up toward the center of the tubules, these black elements being the matur sperm or male germ cells. I would like to call attention to this thin line around the base of the tubule. This is what is called the basement membrane and with change or disease or atrophic condition of the testes, [86] this becomes very thick and interferes with the passage or intrusion from these areas outside of the tubules into the germ cells. Like all epithelia, there are no blood vessels in the germinal epithelium. Nutritive materials or food materials must pass through this material, in through the center of the tubule, and, if that thickened as it has in cases of testicular atrophy, then a further atrophic change is brought about because of the ineffective passage of food materials. In the space between the tubules are cells that we call interstitial cells. It is these cells which produce the testosterone we have been hearing about today. May we go on with another slide? This, I think, shows well the pituitary testicular axis that we mentioned, the pituitary here shown diagrammatically, with two hormones, the FSH hormone and the ICSH, that is to say the follicle stimulating hormone and the interstitial cell stimulating hormone. This is to represent the testes and its two components, tubules and interstitial cells. The FSH factor stimulates the tubules producing spermatazoa. The ICSH factor or hormone stimulates

(Testimony of Warren Nelson, M.D.)

the interstitial cells to produce testosterone. As we said before, there is an interplay between the testosterone produced in the testes and pituitary. If the level of testosterone gets high, it shuts off the production of these gonadotrophin hormones FSH and ICSH and, as a consequence, the target hormones of the testes are not stimulated. [87] The level of the testosterone drops. Then the pituitary springs into activity and these hormones are secreted and again we have the testes stimulated. I think it is important to bear in mind that balance, that sort of a thermostatic arrangement between the testes and the pituitary.

Q. One question. This pituitary gland is situated where in the body, Doctor?

A. It is in the head, commonly said to be at the base of the brain. It is a very small gland, not much larger than a good-sized pea but it is a very important gland because it produces hormones other than those I have mentioned here, hormones that are important in controlling the function of the thyroid, the adrenals and probably the pancreas. This shows, in essence, again what I have just gone through and a little more graphically. There is the general shape of the pituitary up there. This is the testes. These are two parts of the testes, seminiferous tubules and interstitial cells. The tubules, of course, produce the sperm and the interstitial cells producing testosterone. And testosterone has many effects on the body both in the growth of the

(Testimony of Warren Nelson, M.D.)
beard and distribution of hair, including scalp hair, muscular growth, growth of the penis and other organs of male reproduction. [88]

The Witness: This slide shows the changes through puberty, from the pre-pubertal boy to the adult man, and as the testes increase in size they produce the testosterone that causes growth of the penis, it causes the growth of body hair, the ciliary hair and pubic hair and causes growth of the muscles, it causes enlargement of the larynx so that the voice changes, appearance of the beard and recession of hair in the scalp region.

And down here, the growth of the prostate. And, of course, the prostate will not grow without testosterone.

Next, just to illustrate the point, I tried to make about the importance of this interplay between the pituitary gland and the testes, these slides are slides taken from the entire reproductive system of laboratory animals, in this case the rat, the testes. Here is the sperm duct, the sperm ducts, the seminal vesicle, the prostate here at the base of the bladder—and there are other glands that we won't bother to name now—this is the reproductive system of a normal adult male rat. It looks very much like the same system does in the human being.

Next. Now, if that pituitary gland is removed by surgical operation, then the testes become atrophic, and the injection of the gonadotrophic hormone will restore them to normal. If the pituitaries are removed, then the sperm are not pro-

(Testimony of Warren Nelson, M.D.)

duced and the hormones of the testes are not produced, but both [89] of those functions, sperm and hormone production are restorable by giving injections of pituitary extracts.

However, next, in such an animal, without its pituitary, the pituitary hormones are injected by means of extracts. Then, the hormones which were removed by the removal of the pituitary are again supplied and the testes are returned to normal, they again produce sperm, they again produce hormones by the growth of the seminal vessels and the prostate.

Now, to transfer this briefly to the human being, there are conditions in men in which the pituitary fails to function normally in producing the gonads, stimulating hormones. We call such individuals eunuchoids. They are castrate-like individuals. Those individuals fail to go through puberty, and if we take a sample of their testes (this was done in this case) we find the tubules are very small, they are like the tubules of a boy before he enters puberty. In the space between the tubules there are no interstitial cells and, consequently, the individual is producing no testosterone and as a consequence he does not go through puberty. In such an individual we recognize them expressly only by taking a sample of the testes and seeing its picture, and if such an individual is given gonadotrophic hormone, then, in five or six months this picture can be produced in essentially normal testicles with tubles producing sperm and interstitial

(Testimony of Warren Nelson, M.D.)
cells in between these spaces between the tubules, and such an [90] individual passes through puberty under the influence of this stimulus to the testes.

Q. (By Mr. Elson): Doctor, did I understand you to say that with a eunuchoid or a person who was not passing through puberty, or not developing there, that the administration of testosterone would tend to make those cells in the testes grow towards normal and he would tend to become more of a normal person?

A. No. I said that gonadotrophic hormone, a gonad stimulating hormone, the gonadotrophic hormones are the ones that are missing and therefore they are the ones that we attempt to supply.

Q. Let me ask you this, though, isn't it customary with a eunuchoid to administer testosterone to him?

A. It is not in the case of our group. We first determine the condition of their testes and see whether we can't make the patient's own testes produce testosterone.

Q. But the literature is quite replete with instances wherewith eunuchoids they have injected testosterone, isn't that true?

A. In some eunuchoids, and we can determine such eunuchoids by getting a sample of the testes or by making certain urine tests. In some eunuchoids the testes are not susceptible to stimulation. When that is the case, when there is a failure of the testes, then it is proper to give testosterone, but

(Testimony of Warren Nelson, M.D.)

if [91] there is a failure of the pituitaries, the pituitary serum should be given.

Q. In the majority of cases, would you say that testosterone is not administered?

A. I would say in the majority of instances the testosterone has been administered, in some instances incorrectly because the case was not properly diagnosed. But we are just coming now to recognize the differences in these eunuchoids and ways in which to differentiate between them.

Mr. Danielson: You are not speaking, Doctor, solely of the eunuchoid group, though, is that not correct?

A. That is right. I am speaking about eunuchoids now.

Q. (By Mr. Elson): When you say you are just coming now to do that, what do you mean?

A. Well, five years, that isn't very long in terms of medical history.

Q. I understand. That is all. I was sorry to interrupt you.

A. It is quite all right.

Now, to go in reverse, showing that testes can be stimulated by gonadotrophins—that pituitary hormones would stimulate the testes, what happens in the human testes, I have shown where gonads are removed. For example, here is a biopsy taken from a testes of a man in which treatment of estrogen had been indicated. This testes is fairly normal. It produces fair quantities of spermatozoa and it has interstitial cells in the intertubular area. If estrogen is given, this picture is produced, in three

(Testimony of Warren Nelson, M.D.)

or four months a very remarkable and rather complete atrophy of the testes, the reason being that the patient's pituitary was inhibited from the production of hormones that the testes require. This is a case of before and after treatment with estrogen.

However, androgen will do essentially the same thing. This was a pre-treatment biopsy and, three months later, after daily treatment with 25 milligrams of testosterone, the tubules show the evidence of a lack of the pituitary stimulating hormones.

The same is true of the interstitial cells of life, the hormone producing cells, they no longer are normal in function or appearance.

Q. The 25 milligrams you speak of per day, that was injected?

A. That was given by injection, yes, sir.

Next, please.

These are some larger views, pre-treatment condition.

These are the sperm-producing areas, the tubules.

These are the interstitial cells that produce the testosterone, big, fat healthy cells and very evidently functional in appearance.

Next, please. [93]

The same case three months later, after treatment, again with 25 milligrams of testosterone a day, and the atrophic change in the tubules, as well as in the intestitial cells. This latter patient, I forgot to say, had rather definitely normal testes

(Testimony of Warren Nelson, M.D.)

throughout. The biopsy showed a normal picture.

This is a third biopsy taken three months later, after the cessation of treatment, showing that the interstitial cells have returned to normal and the spermatozoa are again present.

Next.

This, again a pre-treatment and a post-treatment picture of the human testes, biopsies again taken from a living individual, before treatment with testosterone and after. This testes was not quite as healthy before treatment and therefore the changes were a little more remarkable and the recovery less remarkable as well.

Next, please.

Now, this is a little bit different case, but I show it simply to emphasize the similarity in appearance between the testes of individuals whose pituitaries have been inhibited by giving androgens or estrogens and testes from individuals who exaggerate, in another way stopped the production of or the action of the gonad stimulating hormones.

I shall not go into the details except to tell you that [94] that is a pre-treatment biopsy and the biopsy taken during treatment and it was a case in which we produced or caused to be produced what we call anti-hormones, hormones which inhibit the activity of the gonad stimulating hormones and that is, when that is done, the testes show this picture which is, as I said, similar to that seen in individuals whose pituitaries have been inhibited from producing the gonad stimulating hormones.

(Testimony of Warren Nelson, M.D.)

Next.

This is the last one, is it?

The Machine Operator: Yes, sir.

The Witness: We will return to a laboratory study, finally. This is a picture of the testes in a rat of 30 days of age. This is just before they go into maturity.

This is a picture at 60 days and this testes is quite mature.

Now, if, at 30 days of age that animal is treated with testosterone, for 30 days, this is the picture that is seen at the end of 30 days, in other words, when the animal is 60 days of age. You see, the testes, instead of maturing from this state to an adult state, it has been halted in the immature condition and has failed, again, to undergo maturation.

However, if at the same time as the testosterone is injected, gonad stimulating hormone is given to the same animal, [95] testosterone plus gonad stimulating hormone——

The Court: What, then, did you say should be given to stimulate?

A. In this case, if I have not made it clear, please tell me again.

The Court: Yes.

A. This animal, at 30 days of age, was given testosterone but at the same time was given gonad stimulating hormone from the pituitary.

The Court: Say it again.

A. Gonad stimulating or gonadotrophic. The

(Testimony of Warren Nelson, M.D.)
hormone is the pituitary that normally stimulates the testes.

The Court: Yes.

A. If it is given along with the testosterone, the development proceeds normally.

Now, the point here to bring out is that when testosterone is given, the testes fail to develop symptoms of this state (indicating). This condition is obtained (indicating). The reason being is that the testosterone inhibits the pituitary from producing these gonadothrophic hormones. But, if in such an animal, that is in an animal whose gonadotrophic hormones have been inhibited, if the gonadotrophic hormones are injected, that is, by extracts made of the pituitary, then, even though the animal's pituitary can't stimulate the testes, the injected hormones do, and we get the picture that normally [96] should have held at the end of those 60-day periods of life. In other words, these two pictures purport to be similar.

Well, I have just simply attempted to——

The Court: What is the gonad?

A. I guess the "gonad" may have been misleading. The gonads are generic terms for the sex glands, either ovaries or testes. It is spelled g-o-n-a-d. And the term gonadtrophic simply means gonad stimulating substances.

* * *

Q. (By Mr. Danielson): Dr. Nelson, on the

(Testimony of Warren Nelson, M.D.)

basis of your education, your professional training and experience, your research, your studies of the literature and conferences with other scientists and doctors and consultations and the research which you have just so graphically portrayed for us, what is your opinion as to the effect on the testes of administered testosterone? By administered testosterone, I am referring to testosterone other than that produced within the body.

A. On the human testes——

Mr. Elson: Wait a minute. Doctor, I want to confine that to methyl testosterone that we are talking about in this case. [97]

Mr. Danielson: Very well, to methyl testosterone, the effect of methyl testosterone.

A. From my own researches, I cannot make any statement on the effect of methyl testosterone.

Q. (By Mr. Danielson): Can you make an opinion on the basis of your professional training, experience, education, your studies of the literature and the results of your conferences and discussions with other scientists and doctors, as to the effect of administered methyl testosterone on the testes?

A. Yes. For instance, methyl testosterone has quantitatively the same effect as testosterone, the effect on the testes is the same.

Q. What would that effect be?

A. The inhibition of sperm cell production and the inhibition of the production of testosterone by the interstitial cells.

(Testimony of Warren Nelson, M.D.)

Q. Would potency as such be a valid indication of whether the interstitial cells producing testosterone are or are not functioning under those conditions?

A. No, because the administered testosterone would, of course, provide the necessary chemical agent for the induction of potency, in other words, the administered testosterone would take the place of the individual's own testosterone, which is no longer being produced in the same [98] amount as before treatment.

Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes?

A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.

Q. Is that the microscopic examination of a slide a portion of the testes——

A. Yes, sir——

Q. Under a slide? A. Yes, sir.

Q. (By the Court): Just how do you get at that? How do you examine the testes under a slide?

A. A small piece of the testes is removed.

Q. (By the Court): By surgical operation?

A. By surgical operation, usually under a very simple local anesthetic. The tissue is properly

(Testimony of Warren Nelson, M.D.)

fixed and sectioned and stained, the usual pathological procedure.

Q. (By the Court): How would that be called for except by just some experiment? That does not seem like a practical thing? Who would have that done?

A. It is being done very, very widely, now.

Q. It is? [99]

A. In cases of infertility or sterility or suspected disease or abnormal function of the testes. It is a widely recognized procedure at the present time.

Q. (By the Court): What prompts it? That is, is it in any sense an examination to determine a cancerous condition?

A. No, not of the testes. Cancer of the testes would usually be evident by rapid growth and swelling of the testes and biopsy would not likely be indicated.

Q. (By the Court): Well, this is the surgical operation, you call that a biopsy.

A. A biopsy is a surgical process or operation in which small samples of the tissue is obtained.

Mr. Danielson: No further questions.

Cross-Examination

By Mr. Elson:

Q. Doctor, you stated among your last answers there that you had had no experience yourself regarding the effect of methyl testosterone on the testes. A. On the human testes, yes.

Q. Yes, but then Mr. Danielson asked you a question, with a long preliminary about your con-

(Testimony of Warren Nelson, M.D.)

tact with others and so on and, as I understood, your answer was that as a result of that, the opinions of these others were that methyl testosterone did inhibit the sperm production. A. Yes.

Q. Now, did you mean that, that in your opinion that is the concensus of opinion?

A. Yes. Yes, sir.

Q. Now, is there any relationship between impotence and sterility?

A. Not a necessary one. They may exist independently or concurrently.

Q. So, when you were speaking of sterility, did you have in mind impotence or simply sterility without regard to impotence?

A. Simply sterility.

Q. Now, is there any comparison (I don't know whether that is the right word or not), but is there any comparison or relationship between the effectiveness or activity of testosterone propionate, as distinguished from methyl testosterone, in the creation of sterility in an individual?

Do I make myself clear?

A. I think you mean is there a relationship per unit weight of material.

Q. (By Mr. Elson): Frankly, I don't know enough about the subject to frame a question that way. But what I mean is this: Your testimony has been that the concensus of opinion is that methyl testosterone inhibits sperm production and tends to cause sterility, am I right? A. Yes. [101]

Q. Now, does testosterone propionate or testos-

(Testimony of Warren Nelson, M.D.)

terone by injection tend more to cause sterility than testosterone administered orally such as methyl testosterone?

A. On the basis of other studies, where the effects of methyl testosterone and testosterone are compared and parallel studies, it requires more by mouth than it does by injection and, therefore, one would expect that it would take more methyl testosterone.

Q. How much more testosterone by injection—or I will put it this way: You part-way answered the question I had in mind next. How much more testosterone by injection would tend to cause sterility in the average case?

A. Any answer I would make there would be purely an estimate and not based upon enough——

Q. It would be conjectural?

A. (Continuing): —scientific information, to warrant it.

Q. (By Mr. Elson): Would you say that 25 milligrams injected three times a week would in the average person tend to cause sterility?

A. It would reduce the production of spermatozoa, it would make him less fertile. I would be unwilling to say that it would make him sterile. Sterility implies complete lack of fertility.

Q. Wouldn't it then follow, Doctor, that 25 milligrams [102] per day in the form of methyl testosterone would even have less effect towards inhibiting sperm production?

(Testimony of Warren Nelson, M.D.)

A. In what type of case do you mean?

Q. Well, let us take a person, Doctor, whom a doctor has diagnosed as apparently suffering from going through the male climacteric or has the symptoms that are associated with that condition?

A. It would depend. The effect of the methyl testosterone or any testosterone would largely be determined by the condition of the patient's own testes. As I tried to show that, that is extremely variable and the degree of effect is conditioned by the degree of normalcy or abnormalcy of the testes.

Q. In other words, if I understand you correctly, is this about it? That if you would take a person such as the one that I have just described and if his testes were producing a very small amount of testosterone, would it be your opinion that the administration of the quantity of methyl testosterone that I have described here would tend to inhibit the sperm production?

A. That is difficult to answer, because you have not told me in your hypothetical case what the condition of his sperm production was before treatment was given.

Q. You mean by sperm count?

A. Sperm count, that would be one measure.

Q. Frankly, I wouldn't be able to include in any hypothetical question anything about sperm count, but let us say, can we put it this way, just generally: that the sperm count was low or the amount of testosterone produced by that individual's testes was low, would methyl testosterone in the quantities

(Testimony of Warren Nelson, M.D.)

that I have mentioned inhibit the production of sperm to the point that you could say that he was tending toward sterility or was going to become sterile?

A. If his sperm production was low, that would be a definite indication that damage had been done, had been undergone by the tubules and, therefore, a methyl testosterone or any testosterone would be more likely to cause damage than in an individual with a high sperm count.

Q. How about a person—can we take one with the average sperm count; let us take a person 50 years old with those symptoms, could we take an average sperm count regardless of what it is, and direct our question, then, to the effect of methyl testosterone on that person?

A. Speaking in general terms, I would say—I would say that the testes of such an individual would be less damaged than the man who had a very low sperm count.

Q. Doctor, what period of time in your opinion would it require for that dosage of methyl testosterone, with that individual, to damage the testes to the point that he became sterile? [104]

A. When you use the term sterile, you are using, as I mentioned a moment ago, a rather final term implying complete lack of fertility.

Q. Can we say non-fertility or not sperm-producing?

A. A completely sterile individual, a permanently sterile one would be one who no longer had germ

(Testimony of Warren Nelson, M.D.)

cells which were multiplying. However, an individual's testes may contain many germ cells and yet, that individual be sterile, and there are all phases and grades from that point on up to what we would regard as the normal testes with the normal germ cell population. So I can't answer in specific terms your question, for that reason. The difference seen between different individuals is extraordinary.

The Court: There would be an extinction, then, of evidence?

A. Yes. When the testicular hormones, testosterone, for example, is given, the production of the pituitary hormones that stimulate the testes is reduced and no longer do the germ cells tend to multiply, in fact, they tend to decrease in number and the degree of effect is not the same in every individual because the condition of the germ cells prior to treatment is so widely variable.

Q. (By the Court): That would not necessarily mean an utterly dead extinction?

A. No. That is right. That is quite correct. [105]

The Court: Both being generic?

The Witness: I have no way of saying——

Mr. Elson: I did not get what the court is referring to. I didn't get the court's question.

(Record read.)

Q. (By the Court): The diminuation of capacity to produce constantly reduced to where there was no production of——

(Testimony of Warren Nelson, M.D.)

Q. (By Mr. Elson): Well, coming back now, Doctor, to the allegations of the information, the information charges that 25 milligrams of testosterone, of methyl testosterone to be taken one tablet or two tablets a day of 25 milligrams per day, in the latter case, that it may cause sterility in the individual. From what you have just said, I take it that that term is incorrectly used, that it may cause sterility, but rather that it would cause an inhibition—— A. Yes, sir.

Q. ——of the growth of spermatozoa in a particular individual?

A. Sterility is a very broad term and I am attempting to define it here in my own terms as I use it in my contact with these individuals, the problems of fertility or sterility.

Q. Now, Doctor, let us leave the 25 milligrams for a moment. Let us assume that we have the same individual and the amount of the product is not 25 milligrams once or twice [106] daily of methyl testosterone but 10 milligrams, would you say that in such individual that 10 milligrams taken in tablet form once a day will really have any inhibitory effect in a material way on such an individual?

A. The likelihood is more remote in that case than in the case of 25 or 50 milligrams a day, but the possibility would exist I believe in the instance of the testes that is already showing signs of atrophy.

Q. Coming back to the point that I had in mind this morning when I asked Dr. Thienes, the inhibi-

(Testimony of Warren Nelson, M.D.)

tory effect on the individual would really be less, though, if he bought and took methyl testosterone himself—strike that.

Assume that a person went to a doctor and the doctor prescribed and injected testosterone propionate. The result is going to be the same, isn't it, on affecting the man's ability to produce spermatozoa as if he had gone to a drugstore and obtained a package of methyl testosterone himself and took it, except that which the doctor injected would tend to be more of an inhibitory agent, would it not?

A. Yes. Of course, in such an instance, I am sure the physician would have warned the individual of the possibility that his fertility would be decreased; he would know the possibility that he faced. If he treated himself, he would not know that.

Q. I beg your pardon? [107]

A. If the patient treated himself, he would not be aware of that possibility.

Q. Do you think that that is the general rule with the general, average practitioner, with a person who the doctor finds is suffering from symptoms associated with the male climacteric?

A. Yes, I think so. The physician has the well-being of his patient at heart and would explain to him the possible beneficial effects of the testosterone as well as its possible deleterious effects.

Q. Don't you think that 25 milligrams once or twice a day of methyl testosterone given to a patient such as I have described over a period of four, five,

(Testimony of Warren Nelson, M.D.)
six weeks, would tend to relieve those symptoms if he were suffering from a hormone deficiency in that period of time?

A. The relief from the symptoms of the male climacteric could be expected in about that time. However, mind you, I said in the case of a male climacteric. I agree with other testimony that has been given that it is an unusual and rarely encountered condition.

Q. So, would you say that if a person manifested those symptoms and took methyl testosterone for that period of time and those symptoms were relieved, that it would be a reasonable assumption that the man was going through the male climacteric? [108]

Mr. Danielson: Just one moment. I assume you are referring to the same symptoms which were brought out in the examination of Dr. Thienes, is that correct, that is, the flushes and so forth?

Mr. Elson: Oh, sure.

* * *

A. I would just like to generalize there. It undoubtedly is a procedure that is done in some instances. In our own case, for example, at the University of Iowa, where individuals come suspected of having the male climacteric, laboratory tests are made to determine whether or not he properly belongs in that category and can be benefited by giving testosterone, or whether he should receive other forms of therapy.

(Testimony of Warren Nelson, M.D.)

Q. (By Mr. Elson): Well, there is a differentiation, is there, between the method of a doctor in your position and others we will say associated with universities or experimental institutions, the method in which they approach a problem and the manner in which it is approached by the average general practitioner?

A. Yes, inevitably that is true. [109]

Q. The economic factors, the factor of time and probably many others enter into it? A. Yes.

Mr. Elson: I have no further questions.

Mr. Danielson: No further questions, your Honor.

Q. (By The Court): Just what is the meaning of the prefix methyl? In methyl testosterone, "methyl," why is that prefix?

A. Are you directing the question to me, sir?

Q. Yes.

A. Methyl I think Dr. Thienes described it this morning is a group of chemical grouping with one carbon and three hydrogens and it is affixed——

Q. I made a note of that at the time, but that does not mean too much to me.

A. Well, in the carbon ring, which is the structural arrangement of these hormones like testosterone, the methyl group is inserted into the ring replacing one hydrogen so that there is testosterone minus one hydrogen.

Q. By adding the carbon group?

A. But plus the methyl group.

Q. Yes.

(Testimony of Warren Nelson, M.D.)

A. The carbon plus the three hydrogens.

Q. Now, you stated, I believe, that this gonad——

A. Gonad—— [110]

The Court: Spell it.

A. G-o-n-a-d.

The Court: I thought it was g-n—gonad was a product of the pituitary gland.

A. The gonadotrophic or gonadic stimulating hormones are products of the pituitary.

Q. (By the Court): Well, is that a hormone generally produced for the market?

A. Yes, such extracts are prepared. They are quite different than the hormones testosterone or estrogen. *They protein* hormones prepared largely from animal tissues.

The Court: I gathered from what you said in explaining the slides there that if there was the definite amount of that hormone mixed with a treatment of the other, that it would have a beneficial effect and overcome deleterious effect of the other while given alone?

A. That is correct.

The Court: I wanted to get that.

The Witness: That was an experiment in which the pituitary hormone was given to replace the animal's own absent pituitary hormones which were absent because their pituitaries had been inhibited by the testosterone.

The Court: Yes. Are there any further questions?

Q. (By Mr. Elson): Just then the court asked

(Testimony of Warren Nelson, M.D.)

a question of Dr. Nelson about the difference or what methyl testosterone [111] was and, though this may answer what the court had in mind, I am going to try it and see if I am not right.

Doctor, testosterone propionate is injected intramuscularly, isn't it? A. Or subcutaneously.

Q. Yes. Methyl testosterone is in the form of tablets and taken orally in the mouth, isn't it?

A. Or they can be injected, too.

Q. Yes. They are usually done, though, some place on the body, aren't they?

A. A small incision is made.

Q. And a pellet is placed therein?

A. Pellets of free testosterone are implanted.

Q. And methyl testosterone is taken orally as a rule? A. Yes; I think more commonly.

Q. And testosterone propionate is injected intramuscularly or subcutaneously? A. Yes, sir.

Q. And isn't it a fact that testosterone propionate is much more potent in its effect than methyl testosterone? A. It is more effective; yes.

Q. In other words, if you will take 25 milligrams of testosterone propionate and inject it into a person, the effect of that would be considerably more than 25 milligrams of methyl testosterone taken orally?

A. It would be; yes. But I don't know what you mean by "considerably."

Q. What is the relationship? Would you say it was three, four or five or 10 times more effective, or is there any way of pointing it out?

(Testimony of Warren Nelson, M.D.)

A. One would have to there, I think, specifically say what activity of the testosterone you had in mind. In the case of the effect on the testes, I have no accurate comparative figures.

Q. This may be a little bit unorthodox in my manner of approach, but it is at least expeditious, I think. In trying to gather this material together, I ran across an article of Charles William Dunn. Are you familiar with that? [113]

A. Yes; I know Dr. Dunn.

Q. It is an article entitled "Diagnosis and Treatment of Testicular Deficiency, Male Hormone Therapy," by Charles William Dunn, in the publication Medical Clinics of North America, November, 1942, Volume 26, at page 1894, where he stated, "The oral preparation, methyl testosterone, has only from one-third to one-fifth the activity per milligram of injected testosterone propionate." Would that fairly reasonably in that connection, if I may ask the question, be the activity or action of the testosterone which he described?

A. I can't accept that statement without going through this thing here.

Q. I will hand it to you and, if you can, without taking too much time, locate it, I will appreciate it.

A. On what page?

Q. Page 1894 of the one I read from and it is marked on the margin with blue ink.

A. One would have to go through a great deal of this to see what exactly he is dealing with.

Q. Speaking generally, I wondered if that would

(Testimony of Warren Nelson, M.D.)

refresh your mind. I don't think it needs to be refreshed. But would it sound like a reasonable comparison to you?

A. In the case of what I think he is dealing with, the growth of pubic and axillary hair and change of the voice, that would be a reasonably comparative figure. In the case [114] of the effect on the testes, I don't know.

Q. I have another article here, "Testosterone Compounds in the Male, Clinical Indications and Methods of Administration," by Hans Lisser and Roberto Escamillo.

Mr. Elson: "The Urological and Cutaneous Review," Volume 46, February, 1942, and at page 92, under the heading of "Oral Methyl testosterone," it is said, "The discovery that the methyl ester of testosterone was effective by mouth constituted a great advance from the standpoint of simplicity and convenience. In our experience, five to eight times the parenteral dose is required orally to initiate definite subjective and objective improvement in severe cases of eunuchoidism." [115]

Would there be an inconsistency between the comparison that the two articles make?

A. Doctors Escamillo and Lisser were speaking in that connection of a comparison between the injected methyl testosterone and the oral testosterone?

Q. That the injected in their opinion would be five to eight times more potent.

A. Methyl testosterone? It is not a comparison

(Testimony of Warren Nelson, M.D.)

between testosterone propionate and methyl testosterone.

Q. It is not?

A. Not in that case that you showed me.

Q. Maybe I read it wrong.

A. It is a comparison between methyl testosterone injected and methyl testosterone taken orally.

Q. I see. The other one was three to five—or one-third to one-fifth, and would your testimony be that in the average case that that would be a fair comparison of the amount of methyl testosterone over and above testosterone propionate that would be necessary to obtain the same effects?

A. I assume you mean testosterone propionate given by injection?

Q. That is correct.

A. Those are figures that have been commonly published.

Mr. Elson: The purpose of this, your Honor, has been to [116] simply try and develop a comparison between the injected product and the one taken orally.

The Court: Yes.

A. May I say again here, however, that those figures do not relate, to the best of my knowledge, to the effect of the testosterone or methyl testosterone on the testes? They are on other structures affected by the male sex hormones.

Mr. Elson: I have no further questions.

(Testimony of Warren Nelson, M.D.)

Redirect Examination

By Mr. Danielson:

Q. What, Doctor, were those other structures of the body which you have just now referred to?

A. The voice, change in the pitch of the voice, pubic and axillary hair and face hair and body strength.

Q. But not the testes?

A. I tried to make that clear, that those studies did not apply to the testes, to the best of my knowledge.

Recross-Examination

By Mr. Elson:

Q. You wouldn't say, though, would you, Doctor, that the inhibitory effect—and this is what we are speaking of so far as the testes are concerned, are we not? A. Yes.

Q. That the inhibitory effect, you wouldn't say, of methyl testosterone, taken 25 to 50 milligrams a day, would be equal over the same period of time to 25 milligrams of testosterone [117] propionate injected three to four times a week?

A. The methyl testosterone taken daily?

Q. Yes.

A. Compared with the testosterone propionate taken three to four times a week?

Q. Yes.

A. At 25-milligram levels in one case and 50 in the other?

(Testimony of Warren Nelson, M.D.)

Q. Yes.

A. That would be 75 against 350. Yes; certainly the orally ingested material would be 350 milligrams a week, equal to 75 milligrams of injected material. That is a difference of about five to one, isn't it?

Q. Just about. In other words, there one would be the equivalent of the other?

A. That would be true on the basis of the figures, which I think are representative.

Mr. Elson: I think that is all.

Redirect Examination

By Mr. Danielson:

Q. Another dosage of another form of testosterone, Doctor, assuming now the same situation, a normal man, and assuming that drug to be say a 5-milligram linguet of methyl testosterone, and the dosage was two tablets three times daily, which is six tablets daily, 5-milligram tablets of methyl testosterone as linguets, do you have an [118] opinion as to whether such an administration might result in sterility?

A. I have no data to base an opinion on there. I would simply have to say that methyl testosterone taken by linguets and, therefore, getting directly into the body circulation and not having to go through the digestive system, would be more likely to be effective at that level than double that amount taken orally.

Q. In other words, in your opinion, it would

(Testimony of Warren Nelson, M.D.)
have double the effect of an equal dosage swallowed or taken orally?

A. Yes, if you understand my affirmation of that being an opinion. I have no definite opinion in that regard.

Mr. Danielson: No further questions.

Mr. Elson: No further questions. [119]

* * *

Mr. Danielson: Dr. Macdonald.

IAN MACDONALD, M.D.

called as a witness on behalf of the government, being first duly sworn, testified as follows:

The Clerk: Your full name, Doctor?

The Witness: Ian Macdonald, M-a-c-d-o-n-a-l-d. The "d" in the last name is not capitalized.

Direct Examination

By Mr. Danielson:

Q. Where do you live, Dr. Macdonald?

A. In Los Angeles.

Q. Of what school or schools are you a graduate?

A. Of McGill University, in 1928.

Q. And what degree was granted to you, please?

A. Doctor of Medicine.

Q. What postgraduate training have you had?

A. At the Montreal General Hospital I had three years of training in general surgery, a year as resident in pathology at the University of Michigan Hospital, and one year as Chief Resident

(Testimony of Ian Macdonald, M.D.)

Surgeon at the University of Toronto Hospital, after which I came out here and became a surgical pathologist at the Los Angeles County Hospital, and I am also doing general hospital work.

Q. Have you had some connection at the University of Southern California, Doctor?

A. Yes; I am Associate Professor of Surgery there and also coordinator of cancer teaching for the School of Medicine.

Q. Are you a member of any medical or other scientific societies?

A. Yes; I am a fellow of the American College of Surgeons and a member of the Cancer Committee of the American College of Surgeons; a member of the American Radium Society; a diplomate of the American Board of Radiology and Radiation Treatment; a member of the Los Angeles Surgical Society.

Q. Have you had any connection with the County Medical Association, Doctor?

A. Yes; at the moment I happen to be chairman of the Cancer Committee of the Los Angeles County Medical Association.

Q. What are the requirements, Doctor, for certification by the American Board of Radiology?

A. In my particular field the requirements are a minimum period of specialized training in the use of X-ray and radium in the treatment of cancer and related diseases and [123] related diseases and, also, a minimum period of experience and back-

(Testimony of Ian Macdonald, M.D.)

ground in the actual use of these agents in the treatment of tumors.

Q. What are those minimum periods, Doctor?

A. Three years of training and two years or more of actual experience.

Q. At least five years?

A. That is right.

Q. What is the function of the Cancer Committee of the American College of Surgeons, Doctor?

A. The Cancer Committee of that organization has been interested in developing information as to the proper method of treatment of various forms of cancer, and in determining what end result was obtained in the treatment of cancer. Of recent years one of the special interests of the Committee has been in the review and collection of information concerning new methods of treatment and their uses and dangers as well.

Q. Have you written and published any articles in medical or other scientific publications?

A. Yes, sir; I have.

Q. About how many have you published?

A. In excess of 20.

Q. Do some of these articles relate to cancer of the breast? [124]

A. Yes; over a third of these I have published has had to do with breast cancer.

Q. Are you engaged in any research of any nature at this time?

A. Yes; I am one of 45 collaborators throughout

(Testimony of Ian Macdonald, M.D.)

the country who are working under the auspices of the Committee on Therapeutic Trials of the American Medical Association.

Q. What is this, Doctor? Will you explain what that is?

A. It is a coordinated effort to try and evaluate the place and usefulness of male and female sex hormones, specifically in the treatment of breast cancer. By obtaining pooled information from a considerable number of investigators, the usefulness of these products can be determined with much greater saving of time than if one had to depend on individual investigators and individual institutions reporting their results, over a much longer period of time.

Q. Are you engaged in the practice of medicine?

A. Yes; I am.

Q. How long have you been so engaged?

A. Since 1932.

Q. Do you specialize in any branch?

A. Yes, sir.

Q. What is that?

A. I specialize in the treatment of cancer and related [125] diseases.

Q. As a surgeon?

A. As a surgeon and, also, using X-ray and radium treatment.

Q. What agents do you use in the treatment of cancer?

A. Surgery, X-ray and radium treatment, al-

(Testimony of Ian Macdonald, M.D.)

most exclusively; a few newer agents in a very limited number of patients.

Q. What would those agents be, just briefly?

A. A relevant example is the use of male and female sex hormones in cancer of the breast.

Q. Would alpha estradiol be one of the female sex hormones? A. Yes; it would.

Q. Have you treated cancer of the breast?

A. Yes, I have.

Q. About how many have you treated?

A. During the last 15 years, in excess of 1,000 cases.

Q. That is in the female human, is that right?

A. That is right.

Q. Have you conducted any studies of other cases of cancer of the breast?

A. Yes; six or seven years ago, I made a review and published an analysis of maybe 2,700 cases of breast cancer from the American College of Surgeons' files. [126]

Q. You have testified that you also use hormones in the treatment of breast cancer, is that correct?

A. In a very limited number of patients; yes.

Q. What hormone do you use in these cases?

A. Both male and female sex hormones.

Q. Why would you use these types of hormones?

A. Because there is an age-determined resistance to the hormone in women who have cancer of the breast. Women who are not yet at their change of life and whose ovaries are still functioning and producing hormones are treated by the male sex

(Testimony of Ian Macdonald, M.D.)

hormone with a beneficial effect in a very limited number of patients. On the other hand, in later life, after the so-called change of life, anywhere from five to ten years after the menopause, the female sex hormone is the agent of choice as far as a hormone is concerned.

Q. When you refer to the male hormones, do you refer to methyl testosterone, for example, or testosterone in any form?

A. Testosterone and androgenic hormones in general; methyl testosterone.

Q. Methyl testosterone is one of these?

A. Methyl testosterone happens to be a specific form of male sex hormone which is used for administration by mouth.

Q. What is the reason for this method of treatment? To refresh your recollection, what would be your reason for using a male hormone in treating a female human patient? [127]

A. Well, it has been established that, although we do not know the ultimate cause of cancer of the breast, certainly one of the necessary factors for its development is an excess quantity of female sex hormones in a younger woman. So, therefore, it seemed rational some years ago, in very advanced cases, who were not otherwise suitable for ordinary methods of treatment, to try the effect of the antagonistic opposite hormone, the male sex hormone, in younger women, with virulent forms of breast cancer. This was a natural development from information already known about the response of

(Testimony of Ian Macdonald, M.D.)
cancer of the prostate to female sex hormones. I think that is the answer that you desire.

Q. You have mentioned that at a certain age the female hormone was used. Will you elaborate on that a little bit?

A. Yes; the rationale for the use of female sex hormones in any cancer of the breast is far from clear because it seems unlikely that the agent which originally played an important part in the development of a form of cancer should be of any use in the treatment of such a tumor; but it was found in women past their menopause, and particularly in quite elderly women, the use of female sex hormones did have in a certain number of them a distinctly inhibitory effect upon the growth of the cancer. [128]

Q. (By Mr. Danielson): You previously referred to younger women. By younger women you mean what, Doctor?

A. I mean women in that physiological age period which includes before and up to the menopause.

Q. And by older women you mean women immediately after the menopause?

A. From the point of this discussion, it means women who have passed their menopause by five to ten years or more.

Q. Do you mean that a female hormone should not be used at all until a woman has passed her change of life, for a period of five to ten years?

A. No, I don't mean that. There is a wide field of usefulness for the female sex hormone with

(Testimony of Ian Macdonald, M.D.)

women who do not have cancer of the breast, who are at or near the menopause.

There are a number of situations which exist which are very well relieved by judicious use of the hormone, with competent medical supervision and repeated examination.

Q. Why would these repeated examinations be made, Doctor?

A. Because in certain women, the continued use of the female sex hormone may produce, or may I say that there is evidence to indicate that changes may occur in the breast and uterus which are, to say the least, undesirable, states of overgrowth can occur in the lining of the uterus, for example, and give rise to local overproduction of tissue in the lining [129] of the uterus, which constitute little benign tumors and are referred to as polyps, and either during or after the use of the hormone in such women, alarming bleeding may occur from the uterus. Those are distinct hazards in the use of female sex hormones.

Q. And what would be the danger as a result of this bleeding, what would be the result of such bleeding, in what respect would that be dangerous?

A. For one thing, it is difficult to tell whether such bleeding is a result of the developing growth, malignant or otherwise, in the uterus, or whether it is simply due to a disturbance of the lining of the uterus, from the use of the hormone.

Q. Now, in referring to female sex hormone, I

(Testimony of Ian Macdonald, M.D.)

gather you are referring to such products as alpha estradiol, is that correct? A. Yes.

Q. Would, specifically, a .5 milligram tablet of alpha estradiol be one of these?

A. It would.

Q. Would a .1 milligram tablet of chrystalline alpha estradiol be one of these?

A. Ordinarily, that dosage would not be very significant except in the small section of women who exhibit a very distinct sensitivity to the hormone. [130]

Q. Supposing a tablet of .1 milligram, tablet of chrystalline alpha estradiol were administered three times daily, what would the effect be of such a therapy?

A. That could produce the undesirable results which I described.

Q. Now, Doctor, have you treated or diagnosed cancer of the breast, the human breast, of the female, which in your opinion has been affected by the administration of female sex hormones?

The Witness: You refer now to young women?

Q. Yes.

A. Yes, I have in a very limited number of women certainly noticed some rather alarming signs in an existing cancer of the breast, because of the use of female sex hormone.

Q. (By Mr. Danielson): Doctor, you testified that you have diagnosed and treated such cases in which there was an affectation of this cancer or

(Testimony of Ian Macdonald, M.D.)

carcinoma. In what way were these cancers affected, in what manner?

A. These were young women with existing proved cancer of the breast in which the duration of the cancer and its approximate rate of growth could be determined within reasonable limits. After the administration of the female sex hormone, and within a short time thereafter, there occurred in each of these instances to which I refer, a very rapid and alarming increase in the growth pattern of this breast cancer. [131]

Q. What are your reasons for this opinion, Doctor?

A. The fact that this alarming increase in growth occurred shortly after the beginning of hormone treatment and that the rapidity and growth was entirely inconsistent with the known pattern of growth of the type of cancer of the breast and that there was no other factor to which it could be attributed.

Q. Was this cancer confined to the breast?

A. No. It was not. Not only in the local area where the tumor began in the breast, but also at other sites to which it had spread, did the same increase in growth occur after the female sex hormone was given.

Q. In other words, these remote growths were likewise affected, is that correct?

A. Yes, to such an extent that we now avoid completely the use of female sex hormone in breast cancer in women before their change of life.

(Testimony of Ian Macdonald, M.D.)

Q. Now, Doctor, on the basis of your professional training and education, experience, your studies of the literature, conferences and discussions with other doctors and your own research, do you feel that this phenomena that you have just described—do you have an opinion as to the consensus of medical opinion on that?

A. May I say, authoritative consensus from the literature and from those who have had wide experience is that there [132] is an extremely serious hazard in the use of the female sex hormone in such patients.

Q. (By Mr. Elson): Meaning what cases? Can we have it more specifically?

A. In patients who have a cancer of the breast and who are of this age period.

Mr. Elson: Who what?

A. Who are of this age period.

Q. (By Mr. Danielson): That is the premenopausal group, is that correct?

A. That is correct.

Q. Now, what is your opinion as to the effect of the amount of the female hormone administered in such cases, taking for example an administration of tablets of alpha estradiol containing .5 milligrams of the drug?

The Court: Just a minute. Is that in the manner which administration is made in the cases that the doctor refers to, orally, or otherwise?

Mr. Danielson: Well, that I don't know.

Q. (By the Court): Well, what was the hor-

(Testimony of Ian Macdonald, M.D.)

mone and in what form was it that was administered in these cases where it had a deleterious effect?

A. The hormone which we used was diethylstilbestrol, and it was given by mouth and not by injection.

Q. (By the Court): And in what dosage? [133]

A. Our dosage was five milligrams of strillbestrol anywhere from once to three times daily, in other words, a dosage of five to 15 milligrams per day.

Q. (By the Court): What prompted that treatment? Was it purely experimental?

A. No, sir. It was suggested by the relative amount of female sex hormone which had been found to be effective in cancer of the prostate. We now are finding that considerable less dosages are effective. Actually we are now carrying some elderly women with breast cancer and with good results on as little as 2.5 milligrams per day. It seems to have just as good an effect as the larger doses which we had been using.

Q. (By the Court): Well, in young women?

A. No, sir. We are using it only in elderly women, now.

Q. (By the Court): There is no amount in younger women under the menopause?

A. Under no circumstances, no, sir.

Q. (By the Court): And about how many cases were involved in a treatment where it had such a deleterious effect?

A. We only treated four cases, two of which exhibited this alarming and rapid increase in

(Testimony of Ian Macdonald, M.D.)

growth. That was enough to discourage us promptly, then.

Q. (By the Court): That was here locally?

A. That was here locally.

Q. (By the Court): And what if any similar experiences have been encountered elsewhere?

A. Similar experiences have been encountered by Nathanson in Boston, at the Massachusetts General, with whom I recently talked personally at Chicago and he has treated more women with breast cancer than any other single investigator in the country.

Still another investigator who has had the same experience is Essher at the Memorial Hospital in New York. In both of those places, they look now with extreme misgiving on the use of the hormone in young women with breast cancer.

Q. (By the Court): Have these men written on the subject?

A. No, sir. This information is recent, and it was obtained in definite form for the first time at a conference held in Chicago in April of this year at which the committee on therapeutic trials held a session of these 45 investigators from the country at large, so that the work which had been done and the results obtained and the hazards found to exist could be pooled and discussed, and it was at that meeting that information of this sort came to light in a really forceful fashion.

Q. (By the Court): Over what period in years back has the medical profession used male and fe-

(Testimony of Ian Macdonald, M.D.)

male sex hormones to any extent in the treatment of cancer, in any form? [135]

A. Well, Huggins at the University of Chicago was the first to use a hormone for any form of human cancer, when he began the use of the female sex hormone for cancer of the prostate. That as I remember began about 1937 or '38, which is my recollection.

The first effort at the use of hormone in cancer of the female breast in human was begun in a very tentative fashion in 1941, at the Memorial Hospital in New York.

To my knowledge, the first use of the female sex hormone in breast cancer did not occur until about 1944.

Q. (By the Court): Well, up to date, the standard treatment and the only one that is really known to the homeopathic medical profession is surgery, X-ray and reading?

A. Yes, sir. The very best results that are being obtained from hormone are not curative and there is no indication that it will ever be more than palliative or than just producing an inhibitory effect upon cancer of the breast, usually only for a period of months. In short, the results of the use of hormone in breast cancer have not been nearly as good as the results of hormone control of cancer of the prostate. And in point of fact, both the male and female sex hormone apparently constitutes a distinct hazard in certain women, in that they both

(Testimony of Ian Macdonald, M.D.)
produce an acceleration of growth rather than a control of the tumor. [136]

* * *

Q. (By Mr. Danielson): Doctor, to clarify a couple of points, when you refer to the use of the female hormone in women with favorable results, you are referring to the postmenopausal group, is that not correct?

A. Strictly. and the older the woman, the more apt she is to obtain a good result.

Q. And by postmenopausal you mean a period starting five to ten years after the menopause, is that not correct?

A. That is the definition as set up in April of this year by the Committee, at least five, preferably ten years after the menopause.

Q. And when you speak of using the male hormone or testosterone in a female, with favorable results, you are referring only to the group in the premenopausal age, is that not correct?

A. Largely so, yes.

Mr. Elson: May I have the last question and answer read, please?

(Record read.)

The Witness: That should be qualified, I think, by saying that the use of the male sex hormone in elderly women [137] does not offer the same hazard as the use of the female sex hormone does in younger women, if I have made that clear.

In short, the disadvantage of the male sex hor-

(Testimony of Ian Macdonald, M.D.)

mone in patients who have cancer of the breast and who are elderly is that it is apt to be ineffective rather than dangerous.

Q. (By Mr. Danielson): And conversely, the use of the female sex hormone in the younger women would have what result?

A. Not only almost always ineffective but according to our present information, in probably half of them there is a distinct and serious hazard in this increase in growth.

Q. And, Doctor, when you are referring to this hazardous use or the dangerous effect of the female hormone, would your opinion apply to dosages of .5 milligrams of alpha estradiol administered daily?

A. That I cannot say with certainty, not having used this particular form of the hormone, but I believe on a relative basis, that for that dosage, when continued for a long enough period of time, that these results could occur.

Q. Do you have information, Doctor—do you know the incidence of breast cancer, female human breast cancer, in the United States?

A. Yes. In the U. S. registration area, during the last several years, at any given time there are approximately 80,000 women who have cancer of the breasts, and there are [138] annually 18,000 deaths, per year, from breast cancer.

Q. How are these cancers diagnosed in the early stages, Doctor?

A. Only by surgical removal of a lump on the breast and microscopic proof of the presence of cancer.

(Testimony of Ian Macdonald, M.D.)

Q. That requires special training, does it not, sir?

A. It requires competent surgical service, yes.

Q. Are there any subjective symptoms of breast cancer which would enable a lay person to properly diagnose that?

A. Only one, the presence of a lump in the breast.

Q. And is that a certain diagnosis?

A. Oh, no. A lump in the breast may be 27 other things besides cancer.

Q. Can this lump in the breast—would this lump in the breast, could it be a cancer in the breast too small to diagnose by touch?

A. Certainly.

Q. By feel? A. Certainly.

Q. And would such a cancer likewise be affected by the use of the hormones?

A. Yes, indeed.

Q. Well, Doctor, is it possible for a female human to have a carcinoma of the breast without knowing it? A. Oh, surely. [139]

Q. And without being able to determine it by subjective symptoms?

A. Certainly. Many early cancers of the breast are indicated on routine physical examination, with the woman unaware of the presence of any sort of process in the breast whatever.

Mr. Danielson: No further questions.

The Court: Pardon me a minute before you cross-examine.

Q. Will you tell me what this alpha estradiol drug hormone is, what is it? I don't understand it.

(Testimony of Ian Macdonald, M.D.)

A. The female sex hormones referred to in generic fashion as the estrogenic hormones are considerable in number with the development of a number of different forms of the hormone which differ chemically in some minor respects and some of them are acquired from natural sources such as the blood or urine of pregnant animals. Others are made synthetically in the laboratory.

Q. (By the Court): Why from pregnant animals?

A. Because a pregnant animal has such an excess of the hormone circulating in the blood that it can be recovered in enough quantities.

Q. (By the Court): And that is the reason——

A. Yes, sir.

Q. ——for the cause of the source for the laboratory?

A. Yes. The main portion of the female sex [140] hormone now used, however, is synthetic because it is made quickly and cheaply in the laboratory and has the same effect on tissues in the female that the so-called natural sources of estrogenic hormone accomplish.

Q. (By the Court): Well, synthetically, in what manner, generally speaking?

A. By starving with several chemicals—I know chemistry, you Honor. By diethylstrillbestrol, which is made in a laboratory simply by the chemical fusion of several other chemicals, which when united produce complex molecular changes, estrogenic in its qualities.

The Court: You may go ahead.

(Testimony of Ian Macdonald, M.D.)

Cross-Examination

By Mr. Elson:

Q. Is it your opinion, Doctor, that cancer of the breast is caused by estrogen?

A. No. The ultimate cause of cancer of the breast we do not know, but there are certain necessary preliminary factors which must be present in order that cancer of the breast may develop in a woman, and estrogenic hormone is one of these background causes of breast cancer.

Q. But there has been no definite proof as yet, I take it, that estrogen has been a cause of cancer of the breast?

A. You mean artificially administered estrogen, or [141] natural estrogens within the patient?

Q. Well, let us take natural estrogens within the patient. A. That is established.

Q. It has been?

A. It is authoritative opinion that that is a necessary factor preceding the development of breast cancer.

Q. You mean a necessary factor in that there must be some estrogen there?

A. There must be a certain amount of circulating estrogen over a long period of years in the woman's life, within herself, in order that breast cancer may develop.

Q. Well, do you find in your experience that the incidence of breast cancer is greater with women who have had no children, or women who have had

(Testimony of Ian Macdonald, M.D.)

some children or women who have had a lot of children, or just what?

A. I have statistical information on that subject. The incidence of cancer of the breast is distinctly greater in those women who have not borne children, or who having borne children have failed to nurse them at the breast.

Q. Now, Doctor, is it true that a pregnant woman produces during pregnancy considerable more estrogen that a woman who is not pregnant?

A. That is true.

Q. And the amount of estrogen that the woman produces [142] increases during the period of pregnancy? A. That is true.

Q. Now, coming down to a practical everyday matter, isn't it common and a general thing for many women who have gone to, say, their general practitioner and who have received shots as we say of estrogen or estrogenic substance and thereafter have been put, if I may say, on a maintenance dose of tablets taken orally on prescription, do thereafter and repeatedly have that prescription refilled without having another prescription issued? Do you get what I mean?

The Witness: Yes.

Mr. Elson: Isn't that common?

A. That is common.

Q. (By Mr. Elson): Has it been your experience that it is the common practice of general practitioners to have patients who complain of symptoms that would lead the ordinary doctor to believe

(Testimony of Ian Macdonald, M.D.)

that estrogen would be helpful to have the woman examined to see whether or not a cancer of the breast was present, before prescribing estrogen?

A. Oh, any reasonably competent physician does an adequate physical examination before the use of estrogenic hormone.

Q. I didn't mean that. I do not dispute that, but let us take it here, the information alleges early and incipient cancer of the breast, cervix and uterus. Do you think that [143] it is possible for the average doctor to diagnose an incipient cancer of the breast, keeping in mind the meaning of the word incipient?

A. It is possible for him to detect an abnormal area of thickening or a very small actual lump in the breast which requires removal and microscopic examination.

Q. Would you say that was in its incipiency, just in the beginning?

A. The microscope may prove it to be so.

Q. That might be true under microscopic examination but would you say that would be the usual practice of the general practitioner, keeping in mind here that we are concerned with a carcinoma which is in its early and incipient stage? That is the language that has been chosen in the information, the language being that 5/10 of a milligram of estradiol may accelerate the growth of an early and incipient carcinoma. That is what we are talking about. Do you think that the average general practitioner, to whom a woman went, would be able to diagnose an early and incipient cancer of the breast?

(Testimony of Ian Macdonald, M.D.)

A. I could only say that there are certain states in the breast which precede the actual development of cancer and they are accompanied by a detectable lump or thickening in a part of the breast, which would be apparent to any well-trained general physician and would be an indication to him of surgical removal of that area of the breast.

Q. By the time it had reached that stage, would you say it was in its incipiency? [145]

A. No; it is generally an established cancer.

Q. Isn't it true that, when the cancer has reached that stage, the woman is conscious of something there in her breast?

A. Many such women are not conscious of anything in the breast at all.

Q. Aren't many women very fearful of the possibility that something that might be a little bit out of the ordinary in their breast might indicate a cancer?

A. A certain number of the female population is in that frame of mind.

Q. Don't you think the vast majority of them are conscious of that possibility?

A. No; I certainly don't.

Q. I take it that neither you nor anyone else knows the cause of cancer of the breast?

A. No; the ultimate or the trigger mechanism that actually sets off the cancer we don't know the nature of.

Q. And it logically follows then, of course, that

(Testimony of Ian Macdonald, M.D.)

you are unable to say that estrogen or that anything else is the cause of it?

A. That is hardly accurate. I again return to the fact that in the background of a human breast cancer estrogenic hormone is of importance. Witness the fact that in women who have, for one reason or another, been castrated in [146] early life, and by "early life" I mean their late twenties or early thirties, where they are castrated surgically or by X-ray treatment, the incidence of breast cancer in those women in later life is about 1/20th of the female population which comes up to a normal physiologic change of life.

Q. You know, do you not, that great quantities of estrogen or estrogenic substance are sold by manufacturers in this country? A. Yes, sir.

Q. Am I correct in saying that the principal source, manufacturing source, of that would be the Ciba Pharmaceutical Corporation and Roche-Organon?

A. Yes; they manufacture a good share of it.

Q. Wouldn't it be fair to say that the number of packages of that product that are sold in the United States during the year would run into the hundreds of thousands?

A. I assume it would.

Q. By the way, does a woman produce estrogen after she has passed the menopause?

A. Yes; she does.

Q. In any great quantity ?

A. In a considerably diminished quantity, ap-

(Testimony of Ian Macdonald, M.D.)

parently from the adrenal glands rather than from the ovaries.

Q. Do I understand you to say the incidence of breast cancer occurs more in the pre-menopausal woman or the [147] post-menopausal woman?

A. The peak incidence of breast cancer occurs at and immediately after the menopause. The ages of 40 to 55 account for the time of greatest incidence of breast cancer.

Mr. Elson: The doctor didn't testify to anything other than cancer of the breast, did he?

Mr. Neukom: No; he didn't.

Q. (By Mr. Elson): You spoke of Dr. Nathanson, Ira Nathanson. A. Yes, sir.

Q. Are you familiar with the paper that he wrote that appears in Volume I, Recent Progress in Hormone Research? A. No; I am not.

Mr. Neukom: Show it to him.

A. I am familiar with the journal but not with that paper.

Q. (By Mr. Elson): You consider Dr. Nathanson, I take it from your direct testimony, to be an authority on the subject of breast cancer?

A. Yes; I do.

Q. I am going to read you a statement that he makes under the heading of "Conclusions," on page 281, and ask you if you agree with the statements that he has made——

Mr. Danielson: Your Honor, for the sake of the record, may we have the date of this publication?

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(Testimony of Ian Macdonald, M.D.)

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Mr. Elson: Oh, yes. I beg your pardon. The

(Testimony of Ian Macdonald, M.D.)

publication is entitled "Recent Progress in Hormone Research," Proceedings of the Laurentian Hormone Conference, Volume 1, and the date is 1947, and published by the Academic Press, Inc., of New York.

Q. On page 281, Dr. Nathanson says, under the heading of "Conclusions," "A considerable number of data bearing on the relation of the endocrine hormone to tumors have been accumulated. The administration of sex hormones to experimental animals has resulted in the production and augmentation and the inhibition of benign and malignant tumors. These are really two definite types of tumors in different species as well as certain strains in any one species of animal. Thus, there are other factors that determine the reaction of a tissue to a hormonal stimulus and the susceptibility of an animal to the induction of neoplasm. It is difficult to interpret these facts in terms of human cancer. Nevertheless, they are of extreme importance in the study of the origin and growth of cancer in general."

Would you agree with that statement?

A. I would agree with that and say also that it bears no relevance to what was discussed here this morning. I have made no claim that in the human family estrogen hormone has anything to do with the production of cancer. I would say, first, that inherent in the woman herself there must be an intrinsic [149] production of her own hormone to lay the background for breast cancer, and that in

(Testimony of Ian Macdonald, M.D.)

a woman who has developed a cancer of the breast the female sex hormone may then accelerate an existing cancer of the breast. I, too, don't believe that the use of female sex hormones, given in therapeutic doses, has ever produced a cancer of the breast.

Q. Let's leave the relevancy of anything that you say or that I say for the court to determine.

A. I am sorry you have introduced that. There seems to be a sharp division of ideas here.

Q. Are you familiar with a book entitled "Endocrinology of Neoplastic Diseases—A Symposium," published by Oxford Medical Publications, 1947?

A. Yes, sir. I happen to own one.

Q. One of these volumes? A. Yes, sir.

Q. The particular chapter that I have reference to is again by Dr. Nathanson. It is chapter 6, page 138, entitled "The Relationship of Hormones to Diseases of the Breast," by Ira T. Nathanson, M.S., M.D., Boston, Massachusetts. On page 165 he states: "Attempts have been made to influence the course of cancer of the breast by the administration of hormones. It was found that carcinogenic and hydrocarbons possess the property of retarding the growth of normal and malignant tissues in experimental animals. Since some of these [150] compounds are similar in chemical structure to the estrogens, the latter are now the subject of investigation relating to cancer of the breast. Several of these substances have been used. Observations thus far indicate that they may cause a definite, although

(Testimony of Ian Macdonald, M.D.)

apparently temporary, partial regression of the primary tumor in some patients."

Have you had any similar experience such as Dr. Nathanson related there, Dr. Macdonald?

A. No; I haven't. And this sort of investigating work can be profoundly modified by new experience.

Q. How is that?

A. These conclusions may produce—such early investigative work can be profoundly modified by subsequent experience and, according to my recent contact with Dr. Nathanson in Chicago two months ago, he, himself, has had reason to modify his own views about the use of female sex hormones in women with breast cancer. He, too, has developed I shall say a very reserved attitude toward it.

Q. That isn't unusual, is it, in the case of investigators and research men in the field of medicine, that, within a short period of time after they have arrived at what might appear to be a conclusion on a subject, they may have considerable doubts as to the validity of their former opinion?

A. Yes, sir. That is always the danger of sticking your neck out in print. [151]

Mr. Elson: I don't have any other questions. Well, wait just a moment. Did I understand you to say on direct testimony that—well, Mr. Sturzenacker has just called it to my attention that you made a statement on your direct testimony concerning the amount of alpha estradiol that, in your opinion, would be dangerous in causing the acceleration of the growth of a breast cancer. Did you?

(Testimony of Ian Macdonald, M.D.)

A. Yes, sir; I did.

Q. And what was that?

A. Well, translated, it is that any amount of any form of female sex hormone which is capable of producing a physiologic effect in a woman may adversely affect the course of an existing cancer of the breast.

Q. And, in your opinion, would such an amount be 5/10 of a milligram per day?

A. That can produce a physiologic effect; yes.

Q. Now, let's get back to the incipient breast cancer. Let's just assume for the purposes of the discussion here that an incipient cancer of the breast is diagnosible, that is, you can find it. Is there any clinical evidence with which you are familiar that 5/10 of a milligram of alpha estradiol will cause the acceleration of such a cancer?

A. No, there is no actual specific proof of which I am aware but the theoretic hazard of its possibility is such that I would want to avoid it at all cost. [152]

Q. Isn't it true that the opinion that you hold in that respect might, by the same token, change a year from now, as Dr. Nathanson's opinion on this subject has changed here in April?

A. Yes; no individual at the present time has absolute knowledge concerning the question which you have just propounded.

Q. Did I understand you to say that you consider stilboestrol to have any effect, possible effect, in accelerating the growth of a breast cancer?

(Testimony of Ian Macdonald, M.D.)

A. I sure do.

Q. Do you know whether or not stilboestrol is on the dangerous drug list in California?

A. Yes; it requires a prescription.

Q. And isn't it a fact that alpha estradiol is not?

A. For some reason, it is not.

Mr. Elson: That is all.

Redirect Examination

By Mr. Danielson:

Q. Doctor, you just mentioned that you believe that alpha estradiol is not on the dangerous drug list in California. Do you have an opinion as to whether it should be?

A. I certainly think it should be. If stilboestrol is on such a list, so should alpha estradiol be.

Q. As to the dosages of alpha estradiol which can produce [153] a physiological result, in your opinion, could a dosage of .1 milligram of crystalline alpha estradiol three times daily produce such a result?

A. I believe it could. I personally have not used alpha estradiol but, from my knowledge of its potency, I believe that in a substantial number of women it could do so.

Q. That would be your opinion?

A. Yes, sir.

Q. You have mentioned that the incidence of breast cancer in a human female is greater in women who have never been pregnant than in those who have. Can you explain that, Doctor?

(Testimony of Ian Macdonald, M.D.)

A. Only in terms of the fact that the normal function of the breast should be that of lactation on at least several occasions during a woman's life, and there is both laboratory and experimental evidence and also extremely sound evidence, concerning cancer of the breast in the human female, that the failure of the breast to perform its expected physiologic function produces disturbances in the tissue of the breast as a result of prolonged years of bombarding of the breast tissue by the hormones to which it is subject from the ovary, without the breast going on to perform its proper function in a woman's life. As a result of that long continued stimulation of the breast, without proper function, certain changes are set up which eventually may lead to the development of cancer. [154]

Q. You have mentioned, Doctor, that during hormone therapy of pre-menopausal women there is not only a preliminary examination but periodic examinations during the course of the treatment. What is the purpose of that, Doctor?

A. The purpose of it should be to determine that there have not occurred some of the local overgrowths of tissue in the so-called target organs on which female sex hormone has its effect. If these states of tissue overgrowth have developed, it should be the signal for the discontinuance of the hormone.

Q. The treatment is contra-indicated once such thickenings or lumps appear, is that correct?

A. Usually; yes.

(Testimony of Ian Macdonald, M.D.)

Q. Is a carcinoma or cancer of the human female breast detectable at an early enough stage so that treatment will bring favorable results?

A. Oh, surely.

Q. If such an early detected cancer exists or were accelerated in its growth, could that progress get beyond control?

A. Over a certain period of time; yes.

Q. Thank you. No further questions.

Recross-Examination

By Mr. Elson:

Q. Have you found in the majority of instances you are able to control the growth of a breast [155] cancer so that the patient lives the normal span of life, as she would if she didn't have it?

A. The control of breast cancer depends entirely upon the stage to which the growth has developed and its extension to other sites at the time of surgical treatment.

Q. Do you think that an increase in the metabolic rate of the patient would have any influence on the growth of cancer?

A. There is no evidence to support that idea that I know of.

Mr. Elson: That is all.

Mr. Danielson: No further questions.